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Plaintiff Fiber Research International, LLC*

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA**

OBESITY RESEARCH INSTITUTE, LLC,

Plaintiff & Counterclaim-Defendant,

v.

FIBER RESEARCH INTERNATIONAL,  
LLC,

Defendant & Counterclaim-Plaintiff.

Case No. 15-cv-595-BAS-MDD

**ANSWER & FIRST AMENDED  
COUNTERCLAIMS FOR VIOLATION  
OF THE LANHAM ACT,  
CALIFORNIA UNFAIR  
COMPETITION LAW, AND  
CALIFORNIA FALSE ADVERTISING  
LAW**

DEMAND FOR JURY TRIAL

**ANSWER**

Defendant Fiber Research International, LLC (“Fiber Research”) answers the allegations made by plaintiff Obesity Research Institute, LLC (“Obesity Research”) in its Complaint as follows:

**JURISDICTION AND VENUE**

1. Admitted that the Court has subject matter jurisdiction and that plaintiff seeks a declaration.

2. Admitted that venue is proper.

**PARTIES**

3. Defendant has insufficient information with which to admit or deny, and therefore presently denies the allegations of paragraph 3 of the Complaint.

4. Admitted.

5. Defendant has insufficient information with which to admit or deny, and therefore presently denies the allegations of paragraph 5 of the Complaint.

6. Defendant does not know of any “DOES” and, as such, defendant has insufficient information with which to admit or deny and therefore presently denies the allegations of paragraph 6 of the Complaint.

**FACTUAL ALLEGATIONS**

7. Admitted that plaintiff seeks declaratory relief, but defendant has insufficient information as to plaintiff’s motive in doing so and therefore presently denies the remainder of paragraph 7 of the Complaint.

8. On information and belief, defendant denies that plaintiff’s products contain or contained Glucomannan during any of the relevant time periods. Defendant admits the remaining averments contained in paragraph 8 of the Complaint.

9. Defendant admits it sent a letter to the General Counsel of Obesity Research on or about March 10, 2015. The letter speaks for itself and therefore, to the extent the remaining averments contained in this paragraph characterize or interpret said letter, defendant denies them.

1           10. Defendant admits it sent a letter to the General Counsel of Obesity Research on  
2 or about March 10, 2015. The letter speaks for itself and therefore, to the extent the remaining  
3 averments contained in this paragraph characterize or interpret said letter, defendant denies  
4 them.

5           11. Defendant admits it sent a letter to the General Counsel of Obesity Research on  
6 or about March 10, 2015. The letter speaks for itself and therefore, to the extent the remaining  
7 averments contained in this paragraph characterize or interpret said letter, defendant denies  
8 them.

9           12. Defendant admits it sent a letter to the General Counsel of Obesity Research on  
10 or about March 10, 2015. The letter speaks for itself and therefore, to the extent the remaining  
11 averments contained in this paragraph characterize or interpret said letter, defendant denies  
12 them.

13           13. Defendant admits it sent a letter to the General Counsel of Obesity Research on  
14 or about March 10, 2015. The letter speaks for itself and therefore, to the extent the remaining  
15 averments contained in this paragraph characterize or interpret said letter, defendant denies  
16 them.

17           14. Defendant admits it sent a letter to the General Counsel of Obesity Research on  
18 or about March 10, 2015. The letter speaks for itself and therefore, to the extent the remaining  
19 averments contained in this paragraph characterize or interpret said letter, defendant denies  
20 them.

21           15. Defendant admits it sent a letter to the General Counsel of Obesity Research on  
22 or about March 10, 2015. The letter speaks for itself and therefore, to the extent the remaining  
23 averments contained in this paragraph characterize or interpret said letter, defendant denies  
24 them.

25           16. Defendant admits that plaintiff currently denies all wrongdoing.  
26  
27  
28

**FIRST CLAIM FOR RELIEF**

**Declaratory Judgment – ORI Has No Liability Under the Lanham Act, 15 U.S.C. § 1125 et seq.**

**(By Plaintiff Against All Defendants)**

17. Defendant incorporates by reference its responses contained in paragraphs 1-16 above as if fully set forth herein.

18. Paragraph 18 of the Complaint is a legal conclusion rather than an alleged fact, and therefore presently is denied.

19. Defendant admits plaintiff seeks a determination as set forth in this paragraph, but denies plaintiff has any legal or factual grounds for the determination it seeks.

**SECOND CLAIM FOR RELIEF**

**Declaratory Judgment – ORI Has No Liability Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.**

**(By Plaintiff Against All Defendants)**

20. Defendant incorporates by reference its responses contained in paragraphs 1-19 above as if fully set forth herein.

21. Paragraph 21 of the Complaint is a legal conclusion rather than an alleged fact, and therefore presently is denied.

22. Defendant admits the plaintiff seeks a determination as set forth in this paragraph, but denies plaintiff has any legal or factual basis to the determination it seeks.

**AFFIRMATIVE DEFENSES**

**FIRST AFFIRMATIVE DEFENSE**

23. Defendant is informed and believes and therefore alleges that plaintiff's Complaint, and each and every claim for relief thereof, is barred by the doctrine of unclean hands.

1 **FIRST AMENDED COUNTERCLAIMS**

2 Fiber Research, by and through its undersigned counsel, hereby brings the below  
3 Counterclaims against Obesity Research, alleging the following on personal knowledge or,  
4 where Fiber Research lacks personal knowledge, upon information and belief, including the  
5 investigation of its counsel.

6 **INTRODUCTION**

7 24. Glucomannan is a dietary fiber derived from Konjac, a root vegetable that is  
8 eaten as a food in Asia. Shimizu Chemical Corporation has developed a proprietary, patented  
9 process for extracting and refining Konjac root to produce the highest-quality glucomannan  
10 available in the world, called “Propol.” Numerous clinical studies support the efficacy of  
11 Propol glucomannan in assisting in weight loss, among other health benefits.

12 25. In 2006, Obesity Research introduced a weight loss product called Lipozene,  
13 with a marketing campaign that highlighted Propol’s strong clinical testing results. As a  
14 result, Lipozene has become the United States’ best-selling weight loss product.

15 26. However, while *Propol* is clinically-proven to promote weight loss, Lipozene  
16 contains neither Propol glucomannan, nor any substantially equivalent glucomannan that  
17 would justify Obesity Research relying on Propol clinical studies to support its Lipozene  
18 weight loss claims.

19 27. Rather, laboratory testing shows Lipozene uses cheap knock-off ingredients  
20 designed to mimic Propol glucomannan, but which are, in reality, a poor substitute. Chemical  
21 analysis demonstrates that Lipozene does not contain high-quality glucomannan, but instead  
22 contains cheap, low-quality ingredients like unrefined Konjac root powder and likely  
23 Xanthan Gum, which is frequently used to “spike” the viscosity of cheap weight loss  
24 products. Furthermore, Lipozene is adulterated with dangerous allergens called sulfites,  
25 which Obesity Research does not disclose, instead falsely claiming that Lipozene is “allergen  
26 free.”

27 28. Pursuant to an exclusive sales contract with Shimizu, Fiber Research markets  
28 Propol in the United States. Fiber Research has been injured in its efforts to sell Propol as a

1 result of Obesity Research's unfairly passing off its sub-standard, adulterated, unrefined  
2 Konjac root product as the same or substantially the same as that studied in clinical trials of  
3 Shimizu's Propol glucomannan (even going so far as to call these the "Lipozene Clinical  
4 Studies"). Fiber Research is also injured by the loss of good will to Propol caused by Obesity  
5 Research's passing off an inferior product as Propol.

6 29. Fiber Research is the assignee of Shimizu's legal rights of action in the United  
7 States for any damages incurred by Shimizu by virtue of any unlawful selling or marketing  
8 of products in unfair or unlawful competition with Propol.

9 30. Fiber Research accordingly brings this action both for injuries sustained directly,  
10 and as the legal assignee for injuries sustained by Shimizu, as a result of Obesity Research's  
11 violation of the Lanham Act and California law.

### 12 **JURISDICTION & VENUE**

13 31. This action arises under 15 U.S.C. § 1125(a) and the statutory law of the State  
14 of California. This Court has subject matter jurisdiction over these claims pursuant to 28  
15 U.S.C. § 1331 (federal question), 15 U.S.C. § 1121 (Lanham Act claims), 28 U.S.C. § 1332  
16 (diversity) and 28 U.S.C. § 1367 (supplemental jurisdiction).

17 32. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391(b).

### 18 **PARTIES**

19 33. Defendant and Counterclaim-Plaintiff Fiber Research International, LLC is a  
20 limited liability company organized under the laws of the State of Nevada.

21 34. Plaintiff and Counterclaim-Defendant Obesity Research Institute, LLC is a  
22 limited liability company located in Reno, Nevada and San Diego County, California.

### 23 **FACTS**

#### 24 **A. Shimizu's Propol Glucomannan**

25 35. More than 300 years ago, the Japanese Shimizu family began farming Konjac, a  
26 potato-like root vegetable that has been eaten in Asia for thousands of years.

1           36. Over the centuries, the Shimizu family's business grew, and it began to produce  
2 refined products from the Konjac root, including glucomannan, a dietary fiber.

3           37. Shimizu developed a proprietary way to extract and refine glucomannan to  
4 provide unique properties like long-term stability at body temperature, and high viscosity.  
5 Eventually Shimizu adopted the name Propol® for the glucomannan extracted and refined  
6 using its proprietary processes, and obtained a United States federal trademark registration  
7 for the name.

8           38. During the 1970s, Shimizu began to study the health benefits associated with its  
9 proprietary glucomannan. Through extensive and costly research, Shimizu discovered the  
10 molecular structure of its glucomannan and the mechanisms by which it provided health  
11 benefits. As a result of such research and development, Shimizu has been granted patents in  
12 37 countries, including the United States, relating to its Propol glucomannan.

13           39. Shimizu has continued to fund scientific research on the health benefits of  
14 Propol. More than 60 human trials have been published establishing Propol's numerous  
15 health benefits, including weight loss.

16           40. When extracted and refined according to Shimizu's proprietary process, Propol  
17 aids in weight loss because, when combined with water, the fiber forms a thick gel capable  
18 of trapping dietary fats, preventing their absorption during digestion. In addition, the  
19 glucomannan mixture in the stomach itself makes the consumer feel full, or satiated.

20           41. Human digestion occurs throughout the digestive tract, beginning with enzymes  
21 in saliva breaking down food in the mouth, and then through the stomach and intestines,  
22 during a process that takes about 72 hours from consumption to elimination. At virtually  
23 every stage of digestion, the body is capable of absorbing dietary fats.

24           42. The effectiveness of any such fiber-based product for weight loss depends on  
25 both the amount and duration of its viscosity. The more gelatinous a mixture is, and the longer  
26 it sustains that gelatinousness, the more fat it is capable of trapping, and thus the greater its  
27 benefit to weight loss. Similarly, the more gelatinous a mixture, the greater the feeling of  
28 satiety it provides in the stomach.

43. Shimizu manufactures different grades of Propol, like Propol-A, Propol-TS, and Propol-RS, all of which are produced using proprietary techniques including special growing conditions for the Konjac root, unique processes for extracting the glucomannan, and refining procedures that result in a high molecular weight and viscosity as compared to other dietary fibers. At body temperature, Propol-A's viscosity exceeds 80,000 mPa.S,<sup>1</sup> and maintains viscosity above approximately 75,000 mPa.S for at least 84 hours.

44. Although there are dozens of studies supporting Propol's weight loss efficacy, two Propol clinical trials are particularly relevant to this lawsuit.

45. First, in 1984, researchers published the results of a double-blind placebo-controlled study of 20 obese female subjects during an 8-week period.<sup>2</sup> The active group was given 1 gram of Propol to take 1 hour prior to meals (for a total of 3 grams per day). The control group was given a placebo. No dietary changes were made. Researchers measured changes in body weight, serum cholesterol, LDL and HDL cholesterol, and triglycerides. The study showed in the test group significant mean weight loss of 5.5 pounds (compared to a weight increase of 1.5 pounds in the control group), significant serum cholesterol reduction of 21.7 mg/dl, and significant reduction of LDL cholesterol of 15.0 mg/dl. The results of the study are represented in the following two graphs.

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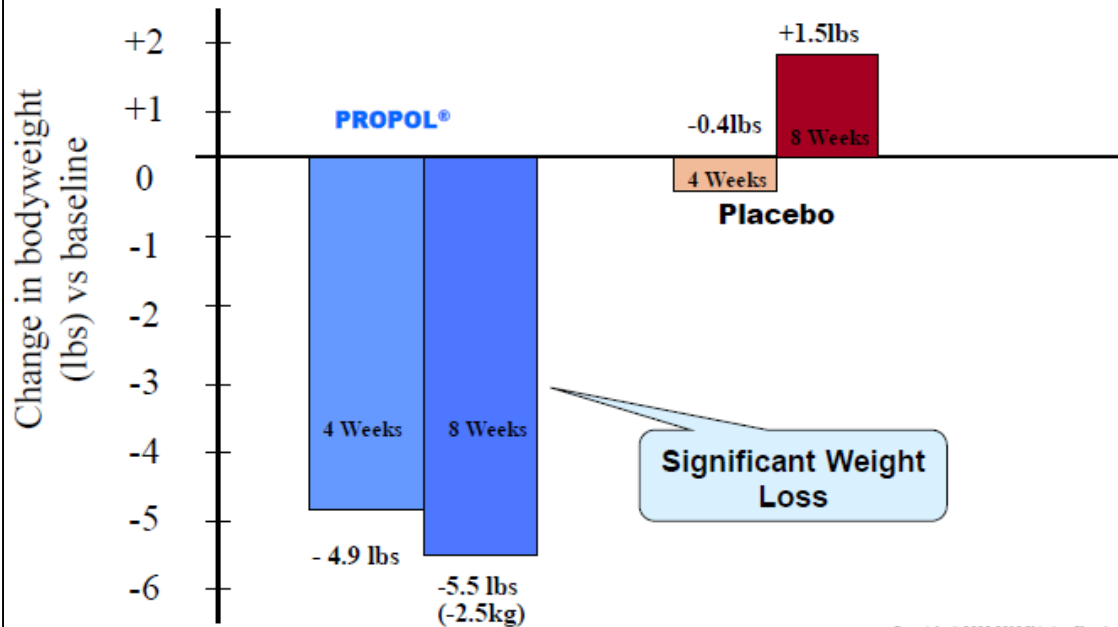
<sup>1</sup> Milli-Pascal seconds, a measurement of viscosity. If a fluid is placed between two plates with a distance of one meter, and one plate is pushed sideways with a shear stress of one pascal (a unit of pressure), and it moves at  $x$  meters per second, then it has a viscosity of  $x$  Pascal seconds. For example, water at 20 degrees Celsius (68 Fahrenheit) has a viscosity of 1.002 mPa.s, while motor oil has a viscosity of about 250 mPa.s.

<sup>2</sup> Walsh, D. E., et al., "Effect of Glucomannan on Obese Patients: A Clinical Study," *International Journal of Obesity*, Vol. 8, pp. 289-93 (1984), attached hereto as Exhibit 1 [hereinafter, "Walsh"].

1) Walsh Study 1

## Weight Loss After 8 Weeks of **PROPOL®** Supplementation 1g/meal

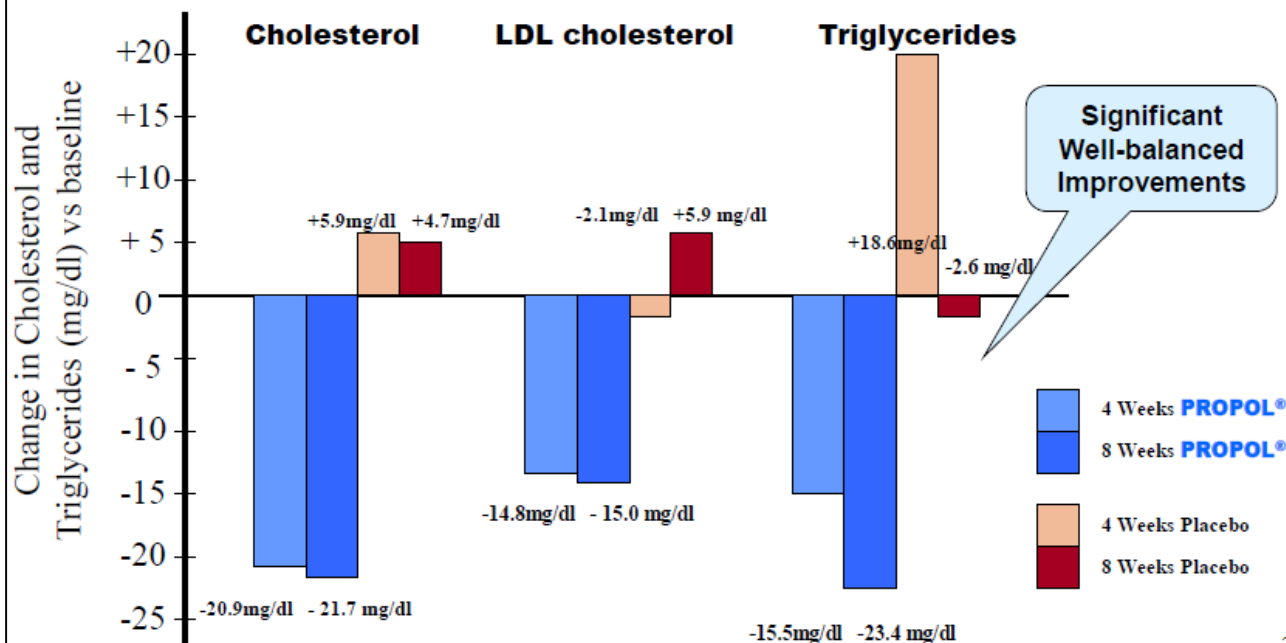
&lt; 3g (0.106oz)/day of "PROPOL®" &gt;



1) Walsh Study 2

## Cholesterol and Triglycerides improvement after 4 and 8 Weeks of **PROPOL®** Supplementation 1g/meal

&lt; 3g (0.106oz)/day of "PROPOL®" &gt;



46. Second, in 2004, a group of researchers presented a paper titled “A Randomized Double-Blinded Placebo-Controlled Study of Overweight Adults Comparing the Safety and Efficacy of a Highly Viscous Glucomannan Dietary Supplement (*Propol*<sup>TM</sup>).”<sup>3</sup> The study compared changes in body composition and blood chemistries between a treatment group taking 3 grams of Propol (1 gram 30-minutes prior to each of 3 meals), and a control group, during a 60-day holiday season study period, and found “a highly significant reduction in scale weight . . . % body fat . . . and fat mass . . . without a loss of fat-free mass or bone density,” which was “consistent with weight losses . . . found in previous studies, but provide[d] the additional finding that virtually all of the weight lost was excess body fat.”

47. Specifically, when comparing those in the placebo group to those in the treatment group who were compliant with both the amount and duration requirements of the study (i.e., consistently took 3 grams of Propol per day, 30 minutes before meals, during the 60-day study), the difference in mean weight lost was 4.93 pounds (treatment group lost 2.75 pounds, while the placebo group gained 2.18 pounds), and the difference in fat lost was 3.86 pounds (treatment group lost 2.47 pounds, placebo group gained 1.39 pounds). *See* Kaats, at 10, 13 (Table 15).<sup>4</sup>

<sup>3</sup> Gilbert R. Kaats et al., “A Randomized Double-Blinded Placebo-Controlled Study of Overweight Adults Comparing the Safety and Efficacy of a Highly Viscous Glucomannan Dietary Supplement (*Propol*<sup>TM</sup>),” *Technical Report* (2004), attached hereto as Exhibit 2 [hereinafter, “Kaats”].

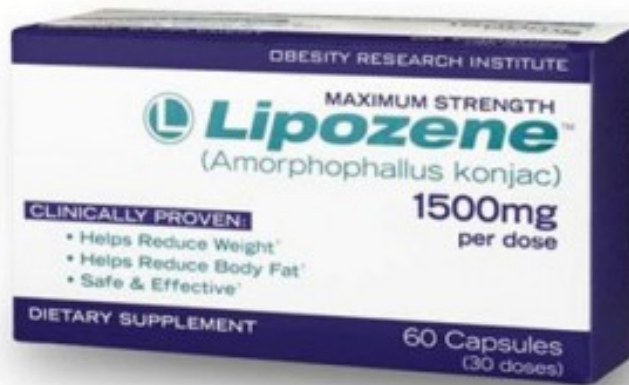
<sup>4</sup> In discussing the results, the researchers noted:

Since no diet/exercise recommendations were provided, participants were free to follow any diet/exercise plan of their own choosing. One could make an argument that participants in a weight loss clinical trial who are willing to expend the time and energy to participate are people who are motivated to lose weight or they wouldn’t participate and that this motivation would include following a diet/exercise of their own choosing. Conversely, an argument could also be advanced that people believing that they may have received an efficacious weight loss supplement, would make no alterations in diet and exercise relying, instead, in on the supplement to achieve their weight loss goals. In either case, what the data do show is that the differences between

**B. Obesity Research Markets Lipozene as “Clinically-Proven” Konjac Root**

48. Obesity Research began marketing Lipozene in 2006, including in online and print advertisements, as well as radio and television commercials and infomercials.

49. Lipozene’s packaging includes a scientific-sounding name for the “active ingredient” in the product, “Amorphophallus Konjac,” which actually means nothing more than penis-shaped Konjac.



50. For many years, in advertising Lipozene, Obesity Research referred generally to clinical proof of its efficacy, but did not specifically identify the publication or paper on which these claims were based.<sup>5</sup>

51. In a commercial that aired no later than February 2007, for example, Obesity Research stated:

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the treatment and the placebo groups suggest that the supplement provided the benefits whether or not they participated in a diet/exercise plan of their own choosing.

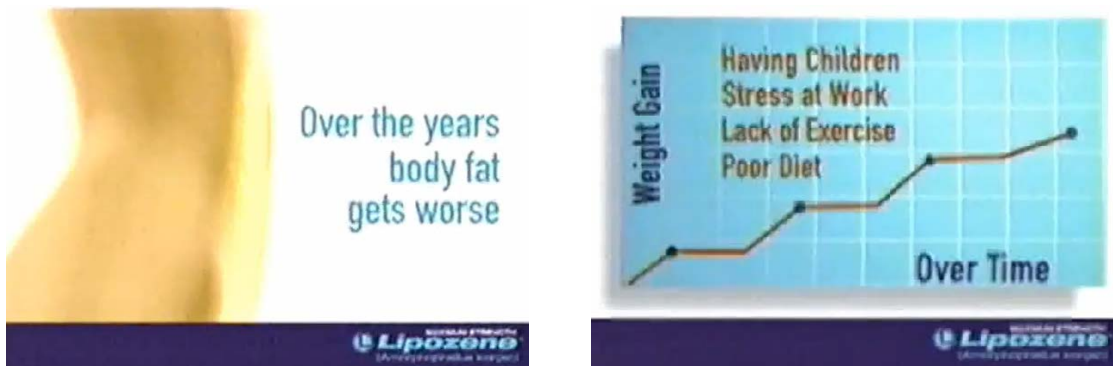
Kaats, at 18.

<sup>5</sup> As a result of Obesity Research obscuring the source of its alleged clinical proof, in January 2012, Los Angeles consumer Martin Conde filed a putative class action lawsuit alleging that while Obesity Research made “numerous efficacy assertions . . . which Defendant states are supported by ‘clinical studies,’ University testing and other ‘research[,]’ . . . [i]n reality, no reliable clinical research or University testing can support the . . . claims made by Defendant,” especially where “[t]hose ‘tests’ and ‘studies’ purportedly relied upon by Defendant are not named or identified by the Defendant, nor are the ‘Universities’ or institutions that allegedly conducted them.” *Conde Compl.* ¶ 13 (attached hereto as Exhibit 3).

1 SPOKESWOMAN: Are you struggling to lose weight? Does it seem  
 2 like, no matter what you do, you just can't seem to get rid of excess body fat?  
 3 It's not your fault. Many of us have simply given up the hope to lose weight.



10 NARRATOR: Body fat builds over our midsection, on top of the  
 11 muscle, underneath the skin, and over the years, it gets worse. Body fat  
 12 increases from having kids, stress at work, lack of exercise, and poor diet.



19 SPOKESWOMAN: The Obesity Research Institute has found the  
 20 solution. It's called Lipozene. Lipozene is clinically proven to help reduce  
 21 your body fat and weight. And, to raise awareness about this weight loss  
 22 breakthrough, the company is letting people try Lipozene risk-free for 30  
 23 days. In a moment, there will be a toll-free number on the screen that you can  
 24 call to receive your risk-free trial. In a recent major university double-blind  
 25 study, not only did participants lose weight, but 78% of each pound lost was  
 26 pure body fat. That's right, nearly all the weight lost is body fat. What's even  
 27 more amazing is that people were not asked to change their daily lives. It's so  
 28 easy. Just take Lipozene. That's it. Now you can get Lipozene over the phone

direct from the manufacturer. If you're ready to get rid of pounds of body fat, then call the number on your screen right now. Lipozene is worth the price, because Lipozene is clinically proven to work.



NARRATOR: Call now to try Lipozene risk-free for 30 days for only \$29.95. Call in the next 10 minutes, and we'll double your order, and pay for shipping, absolutely free. This offer will never be available in pharmacies or drug stores. Remember, Lipozene is clinically proven to reduce your body fat, and weight, or we'll refund your purchase price. Call 1-800-419-3417 to get your free bottle and free shipping with your order of Lipozene. Call 1-800-419-3417. That's 1-800-419-3417.

52. Starting in 2006 or 2007 and continuing to today, Obesity Research has aired about 14 different television commercials nationwide, each of which conveys similar messaging to that of the commercial transcribed above.

53. Despite attempting to conceal the identity of the specific clinical testing to which its Lipozene commercials and advertising have consistently referred, the context demonstrates that Obesity Research has been referring for years to the Kaats study, discussed in paragraphs 46-47, above.

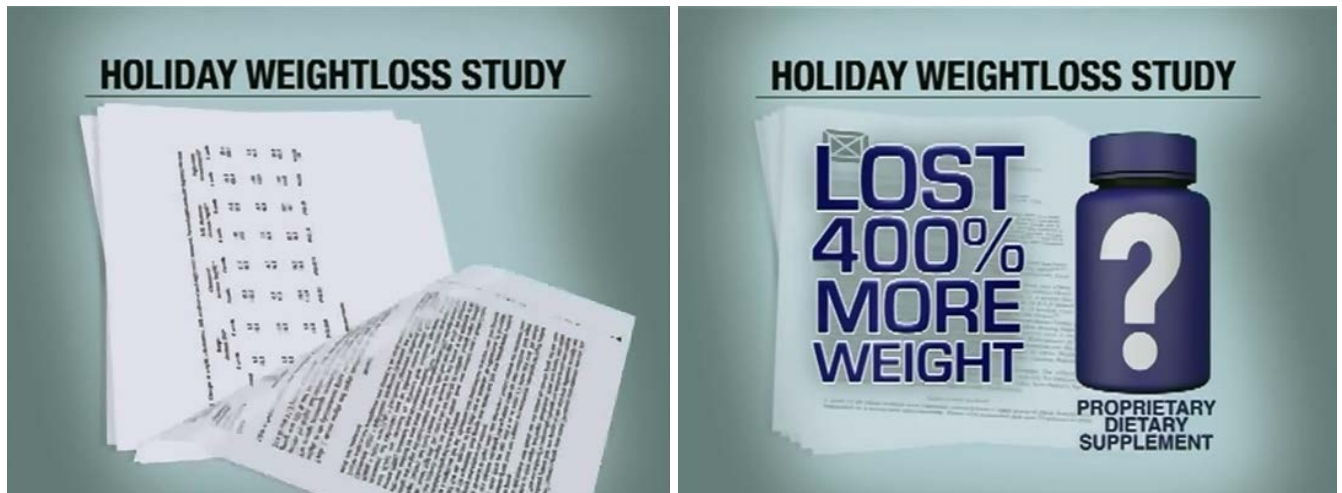
54. For example, many Lipozene commercials contain textual, small-print sentences stating that participants in the clinical study to which the commercials refer lost 4.93 pounds, of which 3.86 was body fat (thus forming Obesity Research's "78% was body fat" figure:  $3.86 \div 4.93 = 0.78296$ ). This was the exact finding in Kaats.

55. In addition, in a recent commercial that aired this past holiday season—December 2014 into January or February 2015—Obesity Research highlighted the fact that the study on which it relies was conducted during the holiday season, as was the Kaats study.

SPOKESMAN: Can you get through the holidays without putting on weight? It's believed the average American gains five pounds or more over the holiday season.



But, thanks to a remarkable holiday weight loss study, people taking a proprietary dietary supplement lost an amazing 400% more weight than people who weren't given this breakthrough weight loss pill. Best of all, this clinical study was designed to be conducted over the holidays. A time when most Americans put on weight, these people lost weight.



So what is this remarkable weight loss supplement? It's Lipozene. And it works so well, it's already sold over 20 million bottles.

And now, for only \$29.95, you can join the countless people who have lost weight with Lipozene. But wait. Call right now and we'll double your order absolutely free. Plus, we'll even pay for your shipping. Remember, Lipozene is clinically proven to help you lose weight without changing your lifestyle. And that's exactly what scientists proved in a groundbreaking clinical study conducted over the holidays, where people who took Lipozene lost an amazing 400% more weight than people who didn't. And of the weight they did lose, 78% was pure body fat.

**Holiday Weightloss Study**  
www.LIPOZENE.com  
CALL NOW 1-800-377-5518

**LOST 400% MORE WEIGHT**  
www.LIPOZENE.com  
CALL NOW 1-800-377-5518

**78% BODY FAT**  
www.LIPOZENE.com  
CALL NOW 1-800-377-5518

CLINICAL STUDY SPONSORED BY OHS WAX DONE UNDER FREE LIVING CONDITIONS. MEANING PARTICIPANTS WERE NOT GIVEN INSTRUCTIONS AS TO DIET AND EXERCISE AND THUS WERE NOT INSTRUCTED TO MAKE ANY CHANGES TO THEIR DAILY LIFESTYLE. CLINICAL DATA SHOWS THAT THE DIFFERENCE IN THE AMOUNT OF WEIGHT LOSS EXPERIENCED BETWEEN THE ACTIVE AND PLACEBO GROUP WAS 4.93 LBS. AND OF THIS 4.93 LBS OF WEIGHT LOSS EXPERIENCED BY THE ACTIVE GROUP 3.85 LBS WAS BODY FAT.

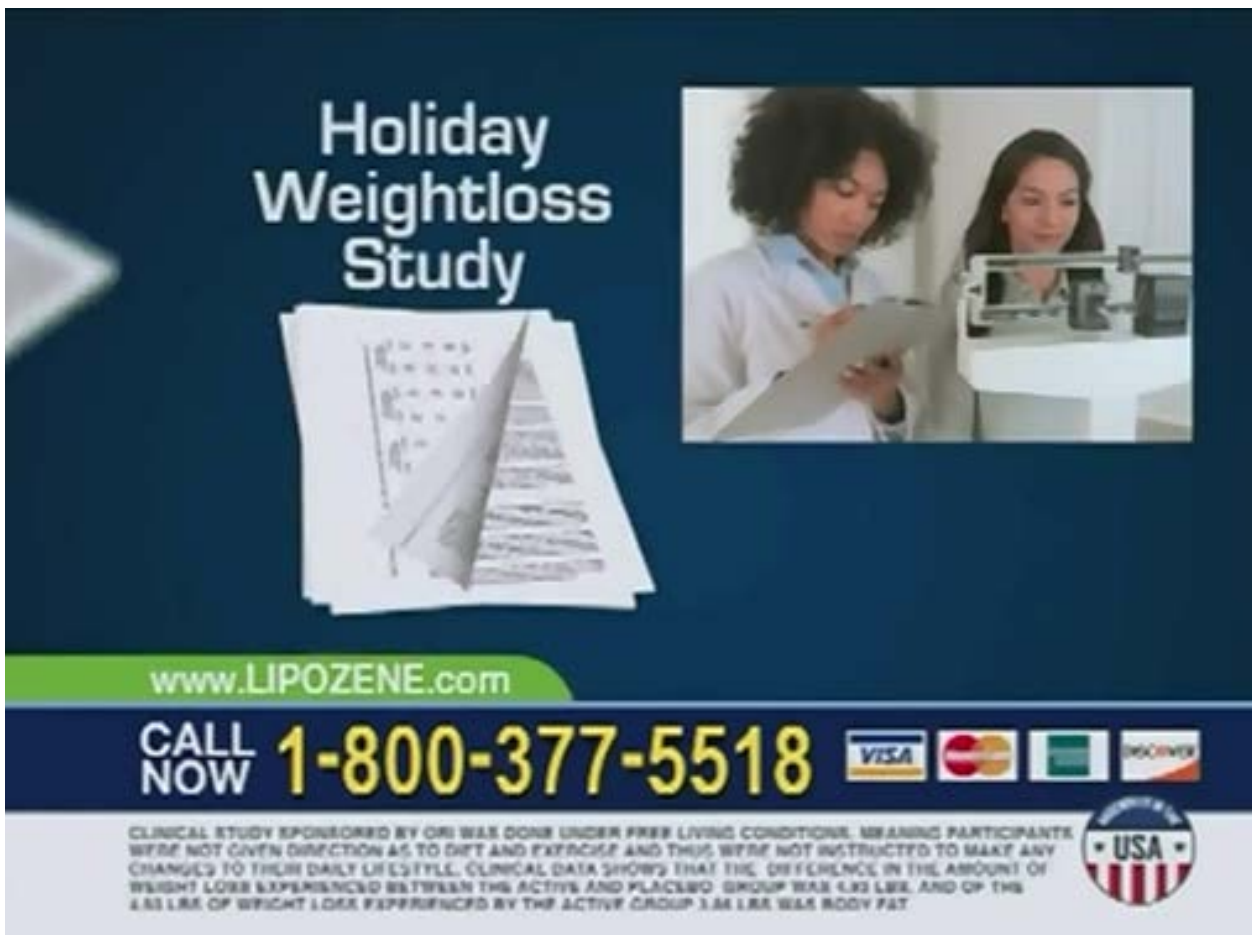
And now, for only \$29.95, you can join the countless people who have lost weight with Lipozene. But wait. Call right now and we'll double your order absolutely free. Plus, we'll even pay for your shipping. But that's still not all. To celebrate selling over \$20 million bottles of Lipozene, we'll give you a free bottle of MetaboUp with your order. That's a \$20 value, free. So instead

1 of putting on weight these holidays like most people do, with Lipozene you  
2 can eat your favorite foods and still lost weight. So call right now.

3 NARRATOR: To order your Lipozene, call 1-800-377-5518. Or log  
4 onto Lipozene.com. Call or log on now.

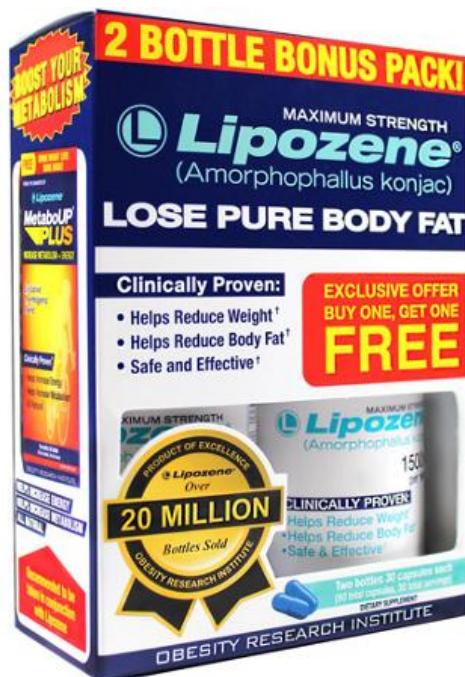
5 56. Obesity Research had no involvement in the 1984 Kaats study. Nevertheless, the  
6 above “holiday season” television commercial, and other commercials, including ones  
7 currently being aired, included the following statement:

8 Clinical study sponsored by ORI was done under free living conditions  
9 meaning participants were not given direction as to diet and exercise and thus  
10 were not instructed to make any changes to their daily lifestyle. Clinical data  
11 shows that the amount of weight loss experienced between the active and  
12 placebo group was 4.93 lbs. and of the 4.93 lbs of weight loss experienced by  
13 the active group 3.86 lbs was body fat.





57. As with its commercials, Lipozene’s packaging has also consistently referred to “clinical proof” of weight loss efficacy.



58. Notwithstanding that Obesity Research's Lipozene television commercials and packaging have relied exclusively on the Kaats study, and despite its prior failure to specifically identify any clinical proof supporting Lipozene's weight loss claims, in approximately September 2012, Obesity Research began referring on its website to three specific papers as comprising the supposed "clinical proof" of Lipozene's efficacy:

a. Walsh, *supra* n.2.

b. Joyce Keithley and Barbara Swanson, "Glucomannan and Obesity: A Critical Review," *Alternative Therapies*, Vol. 11, No. 6, pp 30-34 (November/December 2005) [hereinafter "Keithley"].

c. Nitesh Sood, William L. Baker, and Craig I. Coleman, "Effect of glucomannan on plasma lipid and glucose concentrations, body weight, and blood pressure: systematic review and meta-analysis," *American Journal of Clinical Nutrition*, Vol. 88, pp. 1167-75 (2008) [hereinafter "Sood"].

59. The Lipozene website currently refers to these studies as the "Lipozene Clinical Studies," as shown in the below screen shot (a full version of which is attached as Exhibit 4).

Lipozene - Lipozene Review, What is Lipozene? Official Site

En Español Phone Orders: (800) 998-8763

Home How it Works Reviews FAQs Contact Us

**TRY IT FOR 30 DAYS!** **Try Lipozene Now !**

**TRY LIPOZENE TODAY!**  
MANUFACTURER'S SPECIAL OFFER.  
NOT AVAILABLE IN STORES  
**BUY 1 GET ONE FREE!**  
plus a FREE GIFT of  
MetaboUP Plus & FREE S&H

First Name Last Name United States  
Shipping Address  
City Select State Zip Code  
Phone Email  
**Try it Now** [Loss Weight or your money back](#)

**Lipozene Clinical Studies**

Numerous clinical studies confirm Lipozene's active ingredient, Glucomannan, is safe and effective for weight loss and body fat loss.

**EFFECT OF GLUCOMANNAN ON OBESE PATIENTS: A CLINICAL STUDY**

David E. Walsh, Vazgen YAGHOUBIAN and Ali BEHFOROOS

An eight-week double-blind trial was conducted to test purified glucomannan fiber as a food supplement in 20 obese subjects. Glucomannan fiber (from konjac root) or placebo was given in 1-g doses (two 500 mg capsules) with 8 oz water, one hour prior to each of three meals per day. Subjects were instructed not to change their eating or exercise patterns. Results showed a significant mean weight loss (5.5 lbs) using glucomannan over an eight-week period. Serum cholesterol and low-density lipoprotein cholesterol were significantly reduced (21.7 and 15.0 mg/dl respectively) in the glucomannan treated group. No adverse reactions to glucomannan were reported.

[DOWNLOAD FULL STUDY](#)

**GLUCOMANNAN AND OBESITY: A CRITICAL REVIEW**

Joyce Keithley, DNSc, RN, FAAN, Barbara Swanson, DNSc, RN, ACRN

Glucomannan (GM) is a soluble, fermentable, and highly viscous dietary fiber derived from the root of the elephant yam or konjac plant, which is native to Asia. Preliminary evidence suggests that GM may promote weight loss. This review summarizes studies using GM for weight loss as well as studies investigating its

**C. The “Lipozene Clinical Studies” are Studies of Shimizu Propol Glucomannan**

60. Each of the so-called “Lipozene Clinical Studies” identified on Obesity Research’s Lipozene website, and the “university” study routinely referred to in Lipozene commercials but not on its website (Kaats), is either expressly a study of Shimizu’s Propol glucomannan, or a review of studies that includes studies of Propol.

61. As described above, the subjects of both clinical studies, Kaats and Walsh, were provided Shimizu Propol glucomannan for study.

62. Although Obesity Research refers to Keithley and Sood as “Clinical Studies,” in fact both are simply review papers or meta-analyses, but like Kaats and Walsh, they also discuss clinical studies of pure glucomannan (including many involving Shimizu Propol glucomannan). Aside from the single webpage, none of Obesity Research’s advertising during the past decade has relied on Keithley or Sood to support Lipozene’s weight loss claims.

63. In sum, since late 2006, Obesity Research has been supporting its claims for Lipozene with the Kaats and Walsh studies, both actually studies of Shimizu Propol glucomannan. However, Lipozene is not Propol glucomannan.

**D. Lipozene is Not Propol Glucomannan**

64. From about December 2014 to January 2015, Japan Food Research Laboratories performed a chemical analysis of Lipozene Lot No. 424597, which had been purchased off the shelf from drug stores in the United States exactly as a regular consumer would purchase the product. The results of the analysis demonstrated that a 100-gram sample of Lipozene contained 0.6 grams of Galactose, and 0.2 grams of Glucuronic acid. Galactose and Glucuronic acid are chemical markers of Xanthan Gum, which is used to “spike” cheap glucomannan knock-off products. A true and correct copy of a Japan Food Research Laboratories Certificate of Analysis showing these results, dated January 19, 2015, is attached hereto as Exhibit 5.

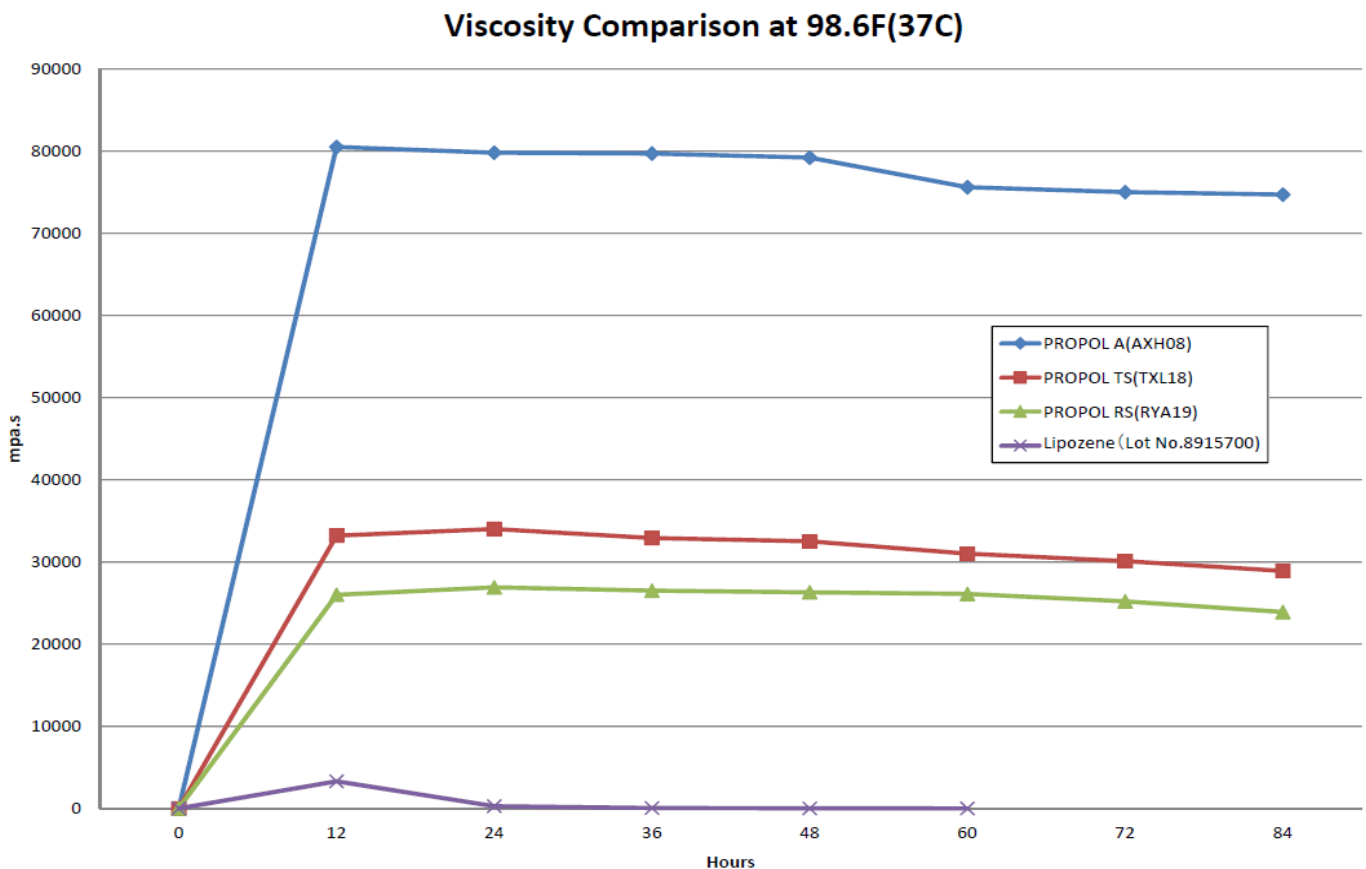
65. The chemical analysis demonstrates that Lipozene, unlike Propol glucomannan or a substantial equivalent, contains poor-quality, cheap ingredients and adulterants that do

not have the same functional chemical profile as Propol. Hence, Lipozene does not have the weight loss benefits of Propol as demonstrated by Propol's clinical testing.

66. Instead, there is no reliable clinical data supporting Lipozene's efficacy in reducing cholesterol, controlling diabetes, or promoting weight loss.

67. Laboratory testing performed by Shimizu from April to November 2014 further demonstrates Lipozene contains quantities of sulfites that exceed the regulatory threshold for labeling, such that Lipozene should be labeled with an allergen warning. But Obesity Research falsely represents on Lipozene's label that there are "No known allergens in this product." True and correct copies of Shimizu Chemical Corporation Certificates of Analyses for testing done on different five different Lipozene lots is attached hereto as Exhibit 6.

68. Shimizu performed a comparative viscosity analysis of several of its Propol products, and Lipozene Lot No. 8915700, the results of which are graphed below:



69. As demonstrated above, Lipozene has a peak viscosity of just 5,000 mPa.s, which lasts at most for 24 hours. Propol products, by contrast, peak at approximately 27,000, 33,000, and 80,000 mPa.s, and sustain their viscosity for the full 84 hours tested.

#### **OBESITY RESEARCH'S FALSE AND MISLEADING STATEMENTS**

70. Since late 2006, Obesity Research has been misrepresenting that the Kaats and Walsh clinical studies establishing the efficacy of Propol glucomannan are clinical studies concerning Lipozene. Obesity Research's statements to this effect (in television and print advertisements, and on Lipozene's packaging) include, without limitation:

- a. "Clinical study proves: 78% of weight lost is pure body fat!"
- b. "Clinically proven!"
- c. "Need to lose body fat? In a Double Blind Study, not only did participants lose weight but 78% of the weight lost was pure body fat!"
- d. "Lipozene is clinically proven to help reduce your body fat and weight."
- e. "In a recent major university double-blind study, not only did participants lose weight, but 78% of each pound lost was pure body fat. That's right, nearly all the weight lost is body fat. What's even more amazing is that people were not asked to change their daily lives. It's so easy. Just take Lipozene. That's it."
- f. "Lipozene is worth the price, because Lipozene is clinically proven to work."
- g. "Remember, Lipozene is clinically proven to reduce your body fat, and weight, or we'll refund your purchase price."
- h. "Researchers have now discovered a capsule that helps remove this body fat, and reduce your weight. It's called Lipozene. Clinically proven to reduce your body fat and weight. In a major university double-blind study, not only did participants lose weight, but 78% of the weight lost was pure body fat. What's even more amazing is that people were not asked to change their daily lives. It's so easy. Just take Lipozene twice a day. That's it."

1 i. “Researchers in a weight loss study didn’t tell people to diet. Instead, they  
2 gave them something else. And remarkably, they ended up shedding pounds and fat.  
3 So what was their secret? They took Lipozene, a breakthrough diet supplement that  
4 allows your body to lose fat without changing what you eat. In fact, Lipozene is so  
5 powerful, 78% of the weight you lose is pure body fat. Not water. Fat.”

6 j. “But, thanks to a remarkable holiday weight loss study, people taking a  
7 proprietary dietary supplement lost an amazing 400% more weight than people who  
8 weren’t given this breakthrough weight loss pill. Best of all, this clinical study was  
9 designed to be conducted over the holidays. A time when most Americans put on  
10 weight, these people lost weight. So what is this remarkable weight loss supplement?  
11 It’s Lipozene.”

12 k. “Remember, Lipozene is clinically proven to help you lose weight without  
13 changing your lifestyle. And that’s exactly what scientists proved in a groundbreaking  
14 clinical study conducted over the holidays, where people who took Lipozene lost an  
15 amazing 400% more weight than people who didn’t. And of the weight they did lose,  
16 78% was pure body fat.”

17 l. “Clinical study sponsored by ORI was done under free living conditions  
18 meaning participants were not given direction as to diet and exercise and thus were not  
19 instructed to make any changes to their daily lifestyle. Clinical data shows that the  
20 amount of weight loss experienced between the active and placebo group was 4.93 lbs.  
21 and of the 4.93 lbs of weight loss experienced by the active group 3.86 lbs was body  
22 fat.”

23 m. “Lipozene is America’s number one selling diet pill, because Lipozene is  
24 clinically proven to work. That’s right. In an independent clinical study, people who  
25 took Lipozene lost weight without changing their lifestyle. That means they were not  
26 asked to change their diet or exercise. They were simply instructed to take Lipozene.  
27 That’s it. And by taking Lipozene, they lost weight. But here’s where it gets really  
28 exciting. 78% of the weight they lost was pure body fat. Not water. Fat.”



1 reputation in the industry has suffered, and Shimizu and Fiber Research have lost sales and  
2 opportunities to make sales.

3 78. Indeed, Shimizu enjoyed a near-100% market share for refined Konjac root  
4 products like glucomannan in the United States in 2000, but currently has only a 2% market  
5 share, with mostly Chinese manufacturers selling what is actually knock-off, unrefined  
6 Konjac root to companies like Obesity Research, for Lipozene.

### 7 **CAUSES OF ACTION**

#### 8 **FIRST CAUSE OF ACTION**

#### 9 **VIOLATION OF THE LANHAM ACT, 15 U.S.C. §§ 1125 *ET SEQ.***

#### 10 **(False Advertising, Unfair Competition, and False Designations in Violation of §** 11 **1125(a)(1))**

12 79. Fiber Research incorporates by reference the preceding paragraphs of its  
13 counterclaims as though fully set forth herein.

14 80. Obesity Research's advertising, marketing and representations for Lipozene are  
15 false and misleading. Obesity Research uses in interstate commerce false, deceptive and/or  
16 misleading descriptions in commercial advertising and marketing that misrepresent the  
17 nature, characteristics, and qualities of Lipozene.

18 81. Obesity Research's false and misleading statements actually confuse and  
19 deceive, or have the tendency to, and are likely to confuse and deceive an appreciable number  
20 of relevant consumers and members of the trade. Obesity Research's false and misleading  
21 statements are material and likely to influence the purchasing decisions of actual and  
22 prospective purchasers of Lipozene and Propol products, and their ingredients.

23 82. Obesity Research's false and misleading statements have diverted, do divert, and  
24 will continue to divert sales to Lipozene at the expense of Propol products, and have lessened,  
25 are lessening, and will continue lessen the goodwill enjoyed by Propol products, if not  
26 enjoined.

27 83. Obesity Research's acts constitute false advertising, unfair competition, and  
28 false designations in violation of the Lanham Act § 43 (a)(1), 15 U.S.C. § 1125 (a)(1).

84. Obesity Research's acts have deceived and, unless restrained, will continue to deceive the public, including consumers and retailers, and have injured and will continue to injure Fiber Research and the public, including consumers and retailers, causing damage to Fiber Research and its assignor, Shimizu, in an amount to be determined at trial, and other irreparable injury to the goodwill and reputation of Propol products.

85. Obesity Research's acts of false and misleading advertising are willful, intentional, and egregious, and make this an exceptional case within the meaning of 15 U.S.C. § 1117(a).

86. Fiber Research has no adequate remedy at law to compensate it for all the damages Obesity Research's wrongful acts have and will cause.

## SECOND CAUSE OF ACTION

### **VIOLATION OF THE CALIFORNIA UNFAIR COMPETITION LAW, CAL. BUS. & PROF. CODE §§ 17200, *ET SEQ.***

87. Fiber Research incorporates by reference the preceding paragraphs of its counterclaims as though fully set forth herein.

88. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice," Cal. Bus. & Prof. Code § 17200.

89. Obesity Research conduct as alleged herein is "fraudulent" within the meaning of the UCL because Obesity Research made, published, disseminated, and circulated false, deceptive, and misleading statements, representations, and advertisements concerning the nature, quality, and characteristics of Lipozene.

90. Obesity Research's conduct as alleged herein is "unlawful" within the meaning of the UCL because it violates at least the following statutes:

- The Lanham Act, 15 U.S.C. § 1125(a)
- The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*
- The False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*
- The California Sherman Act, Cal. Health & Safety Code § 110660

1           91. Obesity Research's conduct with respect to the labeling, advertising, and sale of  
2 Lipozene as alleged herein was "unfair" within the meaning of the UCL because it was  
3 immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of  
4 its conduct, if any, did not outweigh the gravity of the harm to its victims.

5           92. Obesity Research's conduct with respect to the labeling, advertising, and sale of  
6 Lipozene as alleged herein was also "unfair" because it violated public policy as declared by  
7 specific constitutional, statutory or regulatory provisions, including the False Advertising  
8 Law.

9           93. Obesity Research's conduct with respect to the labeling, advertising, and sale of  
10 Lipozene was also "unfair" because the consumer injury was substantial, not outweighed by  
11 benefits to consumers or competition, and not one consumers themselves could reasonably  
12 have avoided.

13           94. As a direct and proximate result of Obesity Research's wrongful conduct, Fiber  
14 Research and its assignor, Shimizu, have suffered injury in fact and lost money or property,  
15 including lost sales and damage to Propol products' goodwill with existing, former, and  
16 potential customers and consumers.

17           95. Obesity Research's wrongful conduct has also damaged consumers.

18           96. These wrongful acts have proximately caused and will continue to cause Fiber  
19 Research and its assignor, Shimizu, substantial injury, including loss of customers, dilution  
20 of goodwill, confusion of existing and potential customers and diminution of the value of  
21 Propol products. The harm these wrongful acts will cause is both imminent and irreparable,  
22 and the amount of damage sustained by Fiber Research will be difficult to ascertain if these  
23 acts continue. Fiber Research has no adequate remedy at law.

24           97. Fiber Research is entitled to an injunction restraining Obesity Research from  
25 engaging in further such unlawful conduct.

26           98. Fiber Research is further entitled to restitution from Obesity Research.  
27  
28

**THIRD CAUSE OF ACTION**

**VIOLATION OF THE CALIFORNIA FALSE ADVERTISING LAW, CAL. BUS. & PROF. CODE §§ 17500, *ET SEQ.***

99. Fiber Research incorporates by reference the preceding paragraphs of its counterclaims as though fully set forth herein.

100. The FAL prohibits any statement in connection with the sale of goods “which is untrue or misleading,” Cal. Bus. & Prof. Code § 17500.

101. Obesity Research knew or in the exercise of reasonable care should have known that, as alleged herein, its publicly-disseminated statements and omissions regarding Lipozene were false and misleading. Obesity Research’s false advertising injured consumers, Fiber Research, and its assignor, Shimizu.

102. By reason of Obesity Research’s conduct, Fiber Research has suffered injury in fact and has lost money or property, including lost sales and damage to Propol products’ goodwill with existing, former, and potential customers and consumers.

103. Obesity Research has caused, and will continue to cause, immediate and irreparable injury to Fiber Research, including injury to its business, reputation and goodwill, for which there is no adequate remedy at law.

104. Fiber Research is entitled to an injunction restraining Obesity Research from engaging in further such acts.

105. Fiber Research is further entitled to restitution from Obesity Research.

**PRAYER FOR RELIEF**

106. WHEREFORE, Fiber Research respectfully requests the following relief:

A. A permanent injunction against Obesity Research, its officers, agents, employees, affiliates, parents, and all persons acting in concert or participation with them who receive actual notice of the injunction by personal service or otherwise, enjoining and restraining them directly or indirectly from falsely advertising, marketing, packaging, labeling, and/or selling Lipozene using any false representations, which misrepresent the nature, characteristics, or qualities of Obesity

Research's goods or other commercial activities or from engaging in any other false advertising with regard to Obesity Research's products.

B. Judgment for the damages suffered by Fiber Research (directly and as assignee of Shimizu's damages) as a result of Obesity Research's false advertising, unfair competition, and deceptive acts or practices, in an amount to be determined at trial, including without limitation as measured by Shimizu's lost sales to Obesity Research and by Obesity Research's Lipozene profits.

C. Judgment for an award of Obesity Research's Lipozene profits attributable to its willful false advertising, unfair competition, and deceptive acts or practices.

D. Judgment trebling Fiber Research's recovery pursuant to 15 U.S.C. § 1117, as a result of Obesity Research's willful and intentional violations.

E. Judgment awarding Fiber Research's reasonable attorneys' fees in this action, pursuant to 15 U.S.C. § 1117, and otherwise as appropriate.

F. Judgment awarding Fiber Research pre- and post- judgment interest, as well as costs of the action.

G. Such other and further relief as the Court deems just and proper.

### **JURY DEMAND**

107. Fiber Research hereby demands a trial by jury on all issues so triable.

Dated: May 28, 2015

/s/ Jack Fitzgerald

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# Exhibit 1

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## EFFECT OF GLUCOMANNAN ON OBESE PATIENTS: A CLINICAL STUDY

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\**Computer Science Department, Moorhead State University, Moorhead, Minnesota, USA.*

An eight-week double-blind trial was conducted to test purified glucomannan fiber as a food supplement in 20 obese subjects. Glucomannan fiber (from konjac root) or placebo was given in 1-g doses (two 500 mg capsules) with 8 oz water, 1 h prior to each of three meals per d. Subjects were instructed not to change their eating or exercise patterns. Results showed a significant mean weight loss (5.5 lbs) using glucomannan over an eight-week period. Serum cholesterol and low-density lipoprotein cholesterol were significantly reduced (21.7 and 15.0 mg/dl respectively) in the glucomannan treated group. No adverse reactions to glucomannan were reported.

### *Introduction*

Fiber in the diet is essential for good health<sup>2,22</sup>. Consumption of fiber has been shown to reduce the occurrence of obesity<sup>2,22</sup> by acting as a bulking agent<sup>2,4,22</sup>. High intake of dietary fiber is also reported to reduce caloric consumption, food ingestion rate, and nutrient absorption<sup>6,19,20,21</sup>.

The type of fiber eaten is also important<sup>12</sup>. Cellulose fiber does not effect serum cholesterol levels<sup>9,17</sup> but pectin gel fiber has been shown to reduce blood serum cholesterol in a number of studies<sup>3,7,8,15</sup>. Glucomannan is a pectin-like gel fiber composed of a polysaccharide chain of repeating units of  $\beta$ -1,4-linked glucose and mannose<sup>16</sup>. Glucomannan is a natural component of konjac root, which has been safely consumed as food for over 1000 years in the Orient<sup>16</sup>.

Studies of human subjects and rats have indicated that glucomannan forms a gel and greatly increases the moisture content of the food bolus during digestion<sup>10,18</sup>. Terasawa *et al.*<sup>18</sup> reported a 23 mg/dl drop in cholesterol over a two-week period while their human subjects were on glucomannan. Kiriyaama *et al.*<sup>10</sup> observed similar results in experiments with rats on hypercholesterolemic diets. One gram of glucomannan will absorb about 100 ml of water *in vitro*. Studies with rats showed that the gel forms around the food particles, causing digestive enzymes to release sugars and fats at a slow rate<sup>10</sup>.

The objectives of the present study were: (1) To determine the effect of glucomannan as a weight reduction aid in obese patients, and (2) To determine the effect of glucomannan on serum cholesterol, triglycerides, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol.

### *Subjects and methods*

A total of 20 obese women were randomly selected from a larger group of obese females who responded to a newspaper advertisement. Those who responded and were 20 percent or more

over their ideal weight<sup>11</sup> formed a group from which 20 subjects were randomly selected. The 20 subjects were randomly placed into two groups of ten with little difference in weight and height distribution. This was achieved by repeatedly selecting two random groups and comparing them with respect to their weight and height distribution. When two groups with similar weight and height distribution were found, one was named the placebo group and the other the glucomannan group.

The glucomannan group took two capsules of a supplement containing 500 mg of purified glucomannan, three times per day, with 8 oz of water, 1 h before each meal. The placebo group took two capsules containing 500 mg starch under the same conditions. Both supplements were identical in shape, color, and appearance. Neither patients nor researchers knew in which group each subject was entered.

Prior to the experiment, both groups were advised that they were participants in a clinical study and that the objective of the study was to determine the effectiveness of the supplement as a weight-loss diet aid. All patients were instructed not to deviate from their previously established eating and exercise patterns.

Each patient's weight and height, without shoes, were recorded using a Health-O-Meter scale, model DQF400. The same scale was used for all weighings. Starting weight (pounds), height (inches), and blood samples were obtained for each person at the beginning of the study; and weight and blood samples were taken after four and eight weeks. The blood samples were analyzed for total serum cholesterol, total triglycerides (TG), and high-density lipoprotein (HDL) cholesterol using an enzymatic method<sup>1,13,14</sup>. Low-density lipoprotein cholesterol (LDL) was calculated by difference from cholesterol, high-density lipoprotein cholesterol, and triglycerides using the following common formula:  $CLDL = C_{Serum} - (CHDL + TG/5)$ , where  $CLDL$  = Low-Density Lipoprotein Cholesterol,  $C_{Serum}$  = Total Serum Cholesterol,  $CHDL$  = High-Density Lipoprotein Cholesterol, and  $TG$  = Serum Triglycerides<sup>5</sup>. Neither subjects nor investigators were advised of the blood chemistry results until after the study was completed.

### Results

Table 1 shows weight and height distribution for the two groups. The average weight in the glucomannan group was 185 lb, in a range from 132 lb to 218 lb. The average percentage overweight of this group was 54.5 percent. The placebo group, by design, had similar characteristics. The average weight in the placebo group was 183 lb and the weight range and percentage overweight were 133 to 214 lb and 51.2 percent respectively.

Table 1. *Patients' starting weight, overweight, and height*

Group	Mean weight (lb)	Weight range	Mean overweight (%)	Mean (in)
Glucomannan	185	132-218	54.5	64.2
Placebo	183	133-214	51.2	63.9
Significant difference	n.s. $P > 0.90$		n.s. $P > 0.70$	n.s. $P > 0.90$

Acceptance of the food supplement was very good. Many subjects indicated that they had a 'full' feeling after taking glucomannan. Observations of satiety were made occasionally in patient interviews, but no complete survey was done. In the future, investigators might measure satiety to determine if there is a statistical significance to this observation. No adverse effects were reported by subjects in either the glucomannan group or the placebo group. There were, however, several in the glucomannan group who reported that the food supplement had relieved mild constipation.

Table 2. Changes in weight, cholesterol, LDL cholesterol and triglycerides measured four and eight weeks after beginning the study

	Weight decrease (lb) *		Cholesterol decrease (mg/dl) *		LDL cholesterol decrease (mg/dl) *		Triglycerides decrease (mg/dl) *	
	4 weeks	8 weeks	4 weeks	8 weeks	4 weeks	8 weeks	4 weeks	8 weeks
Glucosamin group								
Mean = $y_1$	4.9	5.5	20.9	21.7	14.8	15.0	15.5	23.4
s.e.m.	$\pm 1.3$	$\pm 1.5$	$\pm 10.0$	$\pm 9.3$	$\pm 8.2$	$\pm 9.5$	$\pm 20.0$	$\pm 21.8$
Placebo group								
Mean = $y_2$	0.4	-1.5	-5.9	-4.7	2.1	-5.9	-18.6	2.6
s.e.m.	$\pm 1.1$	$\pm 1.5$	$\pm 7.0$	$\pm 6.3$	$\pm 8.5$	$\pm 6.0$	$\pm 11.0$	$\pm 4.3$
Difference between groups								
$y_1 - y_2$	4.5	7.0	26.8	26.2	12.7	20.9	34.1	20.8
s.e.m.	$\pm 1.3$	$\pm 1.4$	$\pm 11.0$	$\pm 8.3$	$\pm 8.0$	$\pm 8.2$	$\pm 26.0$	$\pm 23.2$
Significant difference	$P < 0.02$	$P < 0.005$	$P < 0.03$	$P < 0.024$	$P < 0.10$	$P < 0.05$	$P < 0.10$	$P < 0.20$ n.s.

\*Negative numbers indicate increase in measurement

There were significant changes in weight, cholesterol, LDL cholesterol and triglycerides when the glucomannan group was compared with the placebo group (Table 2). The mean weight loss for the glucomannan group was 5.5 lb in eight weeks. Compared with the placebo group which gained 1.5 lb in eight weeks, the difference in weight loss between the two groups is highly significant ( $P \leq 0.005$ ).

The mean cholesterol for all subjects was 198 mg/dl. This value is high, but is still in the normal range. After four weeks, the glucomannan group had a substantial decrease in cholesterol level of 20.9 mg/dl whereas the cholesterol level for the placebo group increased by 5.9 mg/dl. The difference of 26.8 mg/dl between the two groups was very significant ( $P < 0.03$ ). Variability among subjects was greatest for those who had lower starting cholesterol levels. This result suggests that glucomannan may lower the cholesterol level of subjects who have high cholesterol levels more than those who have normal cholesterol. There was a significant ( $P < 0.1$ ) positive correlation ( $r > 0.6$ ) between the starting level of cholesterol and the decrease in the cholesterol level.

After eight weeks, the glucomannan group maintained a cholesterol level 21.7 mg/dl lower than their initial cholesterol. Cholesterol levels did not, however, decrease significantly between four and eight weeks. This finding indicates that cholesterol levels decrease quickly and remain constant at a depressed level while taking glucomannan.

The mean low-density lipoprotein (LDL) cholesterol for all subjects was 125 mg/dl. After four weeks, the glucomannan group had a mean LDL cholesterol decrease of 12.7 mg/dl when compared to the placebo group. After eight weeks, the difference of 20.9 mg/dl in LDL cholesterol between the two groups was significant ( $P < 0.05$ ). HDL cholesterol did not change significantly during this study. This suggests that the change in cholesterol observed in this study was due to a decrease in the LDL cholesterol.

The change in triglycerides was significant ( $P < 0.10$ ) after four weeks when the glucomannan group was compared with the placebo group. There was no significant difference after eight weeks. Because of the variability of triglyceride data no firm conclusion relating glucomannan intake to triglyceride could be drawn.

### Discussion

Our results agree generally with findings of previous researchers<sup>10,18</sup>. Reduced serum cholesterol was shown when glucomannan (two 550 mg capsules three times per d) was taken. Presumably, glucomannan works in a manner similar to other fibers, by carrying bile out through the intestines and thereby reducing the cholesterol.

The mode of action of glucomannan for weight loss, on the other hand, appears to arise from its bulk-forming properties (3 g of glucomannan will absorb approximately 300 ml of water). This added bulk in the stomach just before each meal, may decrease the appetite and causes the subject to eat less at each meal.

Although the number of subjects used in this study was small, the results support the use of glucomannan food supplement for the purpose of weight reduction and reducing cholesterol in those who have high cholesterol.

*Acknowledgements*—Glucomannan supplied by General Nutrition Corporation (GNC), 921 Penn Avenue, Pittsburgh, PA 15222. Blood analysis performed by the West Fargo Medical Center, P.C., West Fargo, ND 58078, USA.

# *References*

- 1 Bucolo, G. & David, H. (1973): Quantitative determination of serum triglycerides by use of enzymes. *Clin. Chem.* 19, 475-482.
- 2 Duncan, L.J.P., Rose, K. & Meicklejohn, A.P. (1960): Phenmetrazine hydrochloride and methylcellulose in the treatment of refractory obesity. *Lancet* 1, 1262.
- 3 Durrington, P.N., Manning, A.P., Bolton, C.H. & Hartog, M. (1976): Effect of pectin on serum lipids and lipoproteins, whole gut transit time and stool weight. *Lancet* 2, 394-396.
- 4 Evans, E. & Miller, D.S. (1975): Bulking agents in the treatment of obesity. *Nutr. Metab.* 18, 199-203.
- 5 Friedewald, W.T., Levy, R.J. & Fredrickson, D.S. (1972): Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparation ultra centrifuge. *Clin. Chem.* 18, 499-502.
- 6 Heaton, K.W. (1973): Food fiber as an obstacle to energy intake. *Lancet* 2, 1418-1421.
- 7 Jenkins, D.J.A., Leeds, A.R., Newton, C. & Cummings, J.H. (1975): Effect of pectin, guar gum and wheat fiber on serum cholesterol. *Lancet* 1, 1116-1117.
- 8 Kay, R.M. & Truswell, A.S. (1977): Effect of citrus pectin on blood lipids and fecal steroid excretion in man. *Am. J. Clin. Nutr.* 30, 171-175.
- 9 Keys, A., Grande, F. & Anderson, J.T. (1961): Fiber and pectin in the diet and serum cholesterol concentration in man. *Proc. Soc. Exp. Biol. Med.* 106, 555-559.
- 10 Kiriya, S., Morisaki, H. & Yoshido, A. (1970): Changes in hypocholesterolemic activity in rats by various konnyaku powder treatments. *Agr. Biol. Chem.* 34, 641-643.
- 11 Krause, M.V. & Mahan, L.K. (1979): *Food, nutrition and diet therapy*. Philadelphia: W.B. Saunders.
- 12 Kritchevsky, D. (1978): Fiber, lipids, and arteriosclerosis. *Am. J. Clin. Nutr.* 31, S65-S74.
- 13 Leon, L.P. & Stasiu, R.O. (1976): Performance of automated enzymatic cholesterol on SMA 12/60 and autoanalyzer-II instruments (abstract). *Clin. Chem.* 22, 1220.
- 14 Lipid Research Clinics Program (1974): *Manual of laboratory operations, lipid and lipoproteins analysis*. DHEW Publication no. NIH 75 - 628. Washington DC: US Govt Ptg Office.
- 15 Palmer, G.H. & Dixon, D.G. (1966): Effect of pectin dose on serum cholesterol levels. *Am. J. Clin. Nutr.* 18, 437-441.
- 16 Shimizu, M. *Glucomannan Propol<sup>R</sup>, the ultimate dietary fiber*. Hiroshima, Japan: Shimizu Chemical Industries Co. Ltd.
- 17 Stanley, M.M., Paul, D., Gacke, D. & Murphy, J. (1973): Effects of cholestyramine metacumil and cellulose on fecal bile salt excretion in man. *Gastroenterology* 65, 889-894.
- 18 Terasawa, F., Tsuji, K., Tsuji, E., Osima, S., Suzuki, S. & Seki. (1979): The effects of konjac flour on the blood lipids in elderly subjects. *Eiyogaku Zasshi.* 37, 23-28.
- 19 Trowell, H. (1975): Obesity in the western world. *Plant Foods Man* 1, 157-168.
- 20 Trowell, H.C. (1975): Dietary changes in modern times. In *Refined carbohydrate food and disease. Some implications of dietary fiber*, ed D.P. Burkitt & H.C. Trowell. London: Academic Press.
- 21 Van Itallie, T.B. (1978): Dietary fiber and obesity. *Am. J. Clin. Nutr.* 31, S43-S52.
- 22 Yudkin, J. (1959): The causes and cure of obesity. *Lancet* 2, 1135-1138.

# **Exhibit 2**

## **A Randomized Double-Blinded Placebo-Controlled Study of Overweight Adults Comparing the Safety and Efficacy of a Highly Viscous Glucomannan Dietary Supplement (*Propol*<sup>TM</sup>)**

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**ABSTRACT.** This study compared changes in body composition and blood chemistries between a treatment group taking 3 grams (1 gram 30-minutes prior to each of 3 meals) a highly-viscous soluble fiber of Konjac glucomannan (*Propol*<sup>TM</sup>) under free-living conditions for 60-days during the holiday season. A total of 66 women and 17 men completed a baseline and ending Dual Energy X-ray Absorptiometry body composition test and a 42-chemistry blood test. At the end of the study, all subjects completed an anonymous (and subsequently signed) questionnaire to assess study compliance. No differences were found between the treatment and placebo groups on baseline age, weight, body mass index, % body fat, and fat mass. Compared to placebo, the treatment group had a significantly greater reduction in total (-13.9 mg/dl,  $P<0.008$ ) and LDL (-13.7 mg/dl,  $P<0.005$ ) cholesterol. Subjects were dichotomized into Compliant (C) and Non-compliant (NC) sub-groups based on those who reported taking the product as required versus those who did not. As compared to the placebo C sub-group, the treatment C sub-group had a highly significant reduction in scale weight ( $P<0.001$ ), % body fat ( $P=0.01$ ), and fat mass ( $P=0.003$ ) without a loss of fat-free mass or bone density. Within-group comparisons revealed that C subjects in the treatment group had significantly greater improvements in body composition than NC while there were no significant differences between C and NC sub-groups in the placebo group. These results are consistent with weight losses and cholesterol reductions found in previous studies, but provide the additional finding that virtually all of the weight lost was excess body fat. These data suggest that consumption of this supplement can contribute to positive changes in lipid levels and body composition without concomitant adverse side effects.

## **INTRODUCTION**

The U.S. Congress enacted the Dietary Supplement Health and Education Act of 1994 (DSHEA)<sup>1</sup> to address the growing public interest in the potential value of dietary supplements in maintaining optimal health and reducing the risk of disease. In the following year, DSHEA set up the Office of Dietary Supplements (ODS)<sup>2</sup> at NIH in the Dept of Health and Human Services. In January 2004, ODS re-stated its goals and strategies in its Strategic Plan, "*Promoting Quality Science in Dietary Supplement Research, Education, and Communication: A Strategic Plan for 2004-2009.*"<sup>3</sup> One of the five ODS scientific goals is to "Evaluate the role of dietary supplements in the prevention of disease and reduction of risk factors associated with disease."<sup>3</sup>

Perhaps nowhere is this need more important than evaluation of the potential of dietary supplements to combat the global epidemic of obesity. The evidence for the relationship between obesity and a whole host of chronic illnesses is clear. Being obese predisposes to diabetes mellitus, coronary artery disease, stroke, sleep apnea, degenerative joint disease, and most likely certain forms of cancer.<sup>4-7</sup> Report after report continues to outline obesity's soaring costs to society. The latest figures show that each year in the United States alone, obesity leads to medical costs of \$90 billion and 300 000 premature deaths<sup>8</sup> Commenting on the study, HHS Secretary Tommy G. Thompson said:

"Obesity has become a crucial health problem for our nation, and these findings show that the medical costs alone reflect the significance of the challenge. Of course the ultimate cost to Americans is measured in chronic disease and early death. We must take responsibility both as

individuals and healthcare providers working together to reduce the health toll associated with obesity.”<sup>8</sup>

Among its many stated goals, ODS’s goals include stimulation of research on:

- “...how dietary supplements moderate, alter, or enhance metabolic, physiological, and psychological processes associated with maintenance or lack of optimal health...”
- “...using preclinical studies that focus on efficacy and safety which can subsequently be used as the basis for initiation of more extensive (and expensive) clinical trials.”
- “...validation of the accuracy, sensitivity, and specificity of unique biomarkers of dietary supplement effects on known endpoints and their surrogates associated with specific chronic diseases, optimal health, and improved performance”.

This study was designed to be consistent with ODS goals and was designed as a “Pragmatic...” or “Practical Clinical Trial” (PCT) consistent with a September article published in the *Journal of the American Medical Association*.<sup>9</sup> These researchers distinguish between PCTs and “Explanatory Clinical Trials” stating:

Clinical trials designed to assist health care decision makers, referred to as *pragmatic clinical trials* or *practical clinical trials* (PCTs), are defined as trials for which the hypothesis and study design are formulated based on information needed to make a decision.<sup>10</sup> They are distinguished from *explanatory clinical trials*, for which the goal is to better understand how and why an intervention works. Explanatory trials are designed to maximize the chance that some biological effect of a new treatment will be revealed by the study. The PCTs address practical questions about the risks, benefits, and costs of an intervention as they would occur in routine clinical practice.<sup>11</sup> **The most distinctive features of PCTs are that they select clinically relevant interventions to compare, include a diverse population of study participants, recruit participants from a variety of practice settings, and collect data on a broad range of health outcomes [emphasis added].**

In addition to the “distinctive features” or PCTs as cited above, PCTs are often used to decide between non-pharmacological alternatives when decisions are being made as to what treatment plan to recommend to the patient while considering patient satisfaction and costs of treatment. To increase the relevance of the findings, this study was conducted under “real-life” conditions with minimal experimental intervention and over the holiday season, the most difficult time of the year to lose weight<sup>9</sup>.

## METHODS

**Design.** This study used a randomized, double-blinded, placebo-controlled protocol from Sept 2003 to January 2004. The study was approved by the institutional review board at Texas Women’s University and all study participants signed an informed consent which asked them to obtain approval from their personal physicians or health care providers prior to participation. Pregnant or lactating women were excluded from participation and were asked to withdraw if they became pregnant during the study.

**Payment of Incentives.** Other than pregnancy and requiring permission from their family physicians, few restrictions were placed on enrolling subjects in order to recruit a study sample that would most likely represent the end users of the product being evaluated. In view of the high monetary value of the test data to be provided to participants, no financial incentives were provided directly to study participants. However, key members of social and religious organizations were contacted and advised that a \$200 test-completion fee would be paid to participating organizations for each person completing baseline and ending tests irrespective of their compliance to the research protocol. In previous studies, not only has this procedure reduced the time required to recruit study participants, but those recruited reported that they derived more personal satisfaction from contributing to a worthy project than receiving financial incentives.

**Inclusion and Exclusion Criteria.** “Typically, PCTs include a more diverse study population by having broad inclusion criteria and fewer exclusion criteria when enrolling patients. The goal is to enroll patients in the trial with characteristics that reflect the range and distribution of patients observed in clinical practice for a particular problem.”<sup>9</sup> The goal of a PCT is to increase the generalizability of the study results by enrolling study participants that more closely resemble consumers who are likely to use the product being tested. Restricted eligibility criteria often pose concerns for about the extent to which clinical findings can be applied to the ultimate consumer of the product<sup>11,12</sup>. Furthermore, expanding the eligibility criteria “...can also ensure that the higher-risk patients likely to have the greatest benefit from some treatment are not excluded from clinical trials.”<sup>9</sup>

Limitations in the applicability of findings to the ultimate consumer are also posed when the eligibility criteria are based on confirmed diagnosis or specific criteria rather than the study participant's definition of how relevant the product is to them personally. "Because physicians must often treat patients based on the likely rather than confirmed diagnosis, studies that enroll patients based on presenting symptoms rather than definitive test results may be of great practical value."<sup>6</sup> With regard to weight loss studies, a more appropriate eligibility criterion would be whether or not the patient wanted to lose weight—not whether or not they met a BMI or % body fat eligibility criterion.

From the standpoint of exposing study participants to risks, it was impossible to know all of the medical conditions that might be affected by participation in the study and consumption of the dietary supplements, particularly without knowing the subject's personal medical history and medical conditions. Listing the medical conditions that would exclude participation could imply that the investigators know what conditions will be affected by participation and which ones would not, which is rarely, if ever, the case for untested products. Study participants with unspecified conditions might assume that since their medical condition was not listed, there were no risks associated with their condition. To reduce this risk, subjects were asked to provide their personal physicians with a copy of the informed consent and a list of product ingredients to see if they have any medical conditions that would exclude them from the study. When completing and signing the Informed Consent Form participants were asked to certify that they had reviewed their participation with their physicians.

**Dietary Supplement.** The active dietary supplement used in this study, provided subjects with daily amounts of 3 grams of glucomannan Soluble Fiber (GSF) and ~300 mg of calcium. GSF is extracted from the tubers of the Konjac plant and has been used in the Orient, particularly Japan, for over 1,000 years. According to the a description provided by the manufacturer, this unique viscous glucomannan (*Propol™*) water-soluble fiber is produced by special growing conditions of the Konjac tuber and unique extraction and purification procedures which resulting in a high molecular weight and viscosity as compared to other dietary fibers. Previous studies<sup>13</sup> have shown that GSF can decrease appetite, lower serum cholesterol and improve glucose or blood sugar control in diabetics. These studies also suggest that it can reduce the glycemic index of carbohydrates resulting in improved glucose control, lowered insulin levels, and reductions in serum Total and LDL cholesterol. It is believed that lowered insulin levels result in less storage of dietary fat and increased utilization of stored fat. In addition its ability to quickly and profoundly absorb water suggests it may lead to a swelling in the stomach resulting with feelings of fullness, a satiating effect that may result in less food consumption during a meal. The matching placebo was identical in appearance, but contained only an inactive compound. Subjects were instructed to take the supplement 30-minutes prior to each meal with a minimum of 8 ounces of water. No instructions were provided to study participants with regard to diet and exercise and participants were free to follow, or not follow, any diet and/or exercise program of their own choosing.

#### **Randomization**

Using a random numbers chart, the grantor numbered all bottles from 1 to 120 retaining coding of the numbers assigned to the active and placebo bottles. The pre-numbered bottles were sent to the study trustee who in-turn randomly assigned a subject number to each of the pre-numbered bottles and retained a list of which subject number corresponded to which of the pre-numbered bottle. Six bottles were selected at random and set aside for a post-study analysis of the ingredients. As subjects enrolled in the study they randomly selected a subject number from a container and were given the product bottles that were assigned to this subject number. After all subjects completed the study, a computerized list of the subject data was provided to the trustee. The trustee contacted the grantor and asked that the list of active versus placebo numbers be forwarded to him and the trustee provided it to the PI for data analysis.

At the conclusion of the study after the blinding was broken, four of the previously retained bottles contained the active ingredients, two the placebo. Six capsules from each bottle were placed in 4 ounces of water to observe differences in viscosity between the active and placebo. After ~20 minutes, all four of the samples containing the active ingredients showed significant absorption of the water changing to a gelatin-like composition. Neither of the placebo samples showed this change. After 24 hours, the composition of the active sample had become more like gelatin while there was no change in the placebo samples.

**Tests and assessments.** Study participants completed baseline and ending scale weights using a strain-gauge scale (FS-0900, Befour Scale Company, Inc., [www.befour.com](http://www.befour.com)) accurate to within  $\pm 0.1$  lb. In addition to completing baseline and ending vital signs, study participants completed a 42-chemistry blood test and a body composition and Bone Mineral Density (BMD) test as measured by Dual Energy X-ray Absorptiometry (DEXA). "Traditionally, the gold standard for estimating body fat has been hydrodensitometry (underwater weighing), which is based on the principle that fat tissue is less dense than muscle and bone. Dual-energy x-ray absorptiometry is now replacing densitometry as a standard because of its high precision and its simplicity for

the subject".<sup>14</sup> All subjects completed an anonymous post-study critique and evaluation that allowed for the classifications of compliance described below.

**Correcting for compliance.** After completing all ending tests, study participants were asked to complete an anonymous critique of the study that, among other items, asked how closely they followed the research protocol and how many capsules they actually took each day irrespective of what they had reported during weekly check-ins. When completing the questionnaire, participants were asked not to sign it and to be candid about reporting how accurately they reported the information on their weekly tracking forms. They were then asked to place the completed questionnaire in an envelope, seal it and give it to a research technician. Upon receipt of the envelope, the technician explained the importance of obtaining accurate data about product usage, and asked the participant if he/she would put their name on the envelope if given a signed statement insuring confidentiality and that the critique data would be used for research purposes only. A total of 95% (79 subjects) of the subjects signed the envelope. Additionally, after all participation incentive were paid to the subjects, research technicians contacted the subjects by telephone to confirm the data in the ending questionnaire and determine which subjects took the supplement 30 minutes prior to a meal and which ones did not. This allowed for three classifications of study compliance: those who reported taking six Capsules a day ("Amt"), those who took the supplement 30 minutes before eating ("Time"), and those who complied with both requirements of taking 6 a day 30 minutes before a meal ("Both"). Non-compliant subjects were those who did not comply with these requirements.

## STATISTICAL ANALYSES

The percentage of subjects complying to Time, Amt and Both within the treatment group was calculated using a logistic regression model. An interaction model was fit to assess the significance of variation in the association between compliance to Time and treatment group with levels of compliance to Amt. Subjects who complied to Time were contrasted to those who did not comply to Time on mean age and mean baseline percent body fat, weight, fat, fat free mass and bone density using analysis of covariance on the combined cohort; this analysis was repeated within both the treatment and placebo groups. This series was repeated for compliance to Amt and to Both. Analyses of changes proceeded in three steps. First, interaction models were fit to assess the significance of variation in the relation between compliance to Time (and separately to Amt) and treatment group on mean changes in % body fat, weight, fat, fat free mass, body composition index, and bone density. Second, treatment groups were contrasted with regard to mean changes in these six outcome variables with restriction to subjects who complied with Time, complied with Amt, and complied with Both. Contrasts of treatment group means on these six outcomes without accounting for compliance were presented for reference. Third, subjects who complied to Time were contrasted to those who did not on mean changes in the same six outcome variables with restriction to group A; this analysis was repeated for compliance to Amt and for compliance to Both. These three series of within-group contrasts were repeated with restriction to group P. All statistical testing was two-sided and was carried out with a significance level of 5%. Contrasts or interactions with p-values less than or equal to 0.05 were called statistically significant. All analyses were carried out with SAS software (version 8.2).

## RESULTS

### Body Composition: Baseline compliance contrasts

The percentages of subjects in each of the three compliant categories for the active (Group A) and placebo (Group P) groups are summarized in Table 1. As shown, there were no statistically significant differences between the Active and Placebo groups in the percentage of subject who complied with Time ( $p=0.95$ ), Amt ( $p=0.32$ ) or Both. A cross-comparison between Time and Amt in both A and P groups revealed that compliance was greater in both groups with Amt as compared to Time, but these differences were not statistically significant in either group. These data reveal that the percentages of subjects complying with Time, Amt or Both were statistically identical in both groups.

**Table 1. Comparisons of Percentages of Compliant Subjects in Active (A) and Placebo (P) Study Groups**

Group	N	Time	Amt	Both
<b>A</b>				
	38	19 (50.0%)	25 (65.8%)	16 (42.1%)
<b>P</b>				
	42	22 (52.4%)	32 (76.2%)	18 (42.9%)
<b>Total</b>				
	80	41 (51.3%)	57 (71.3%)	34 (42.5%)

Comparisons of baseline ages and body composition measurements between subjects who complied with Time and those who did not in a combined group of the active and placebo subjects are shown in Table 2. These data reveal that the compliant subjects were older (51.2 vs 43.5 yrs,  $P=0.01$ ) than non-compliant subjects. However, there are no statistically significant differences between the compliant and non-compliant subjects on body composition measurements (%fat, weight, fat mass, fat-free mass or bone density [BMD]). All references to "weight", fat mass, fat free mass and body composition improvement index are lbs. References to Bone Mineral Density (BMD) are grams/cm<sup>2</sup>.

**Table 2. Comparisons of Baseline Ages and Body Composition Measurements between Compliant and Non-Compliant Subjects in a Combined Group of Active and Placebo Subjects for Time.**

Outcome Measure	Compliance to Time	N	Mean (SEM)	Compliance Difference	Mean Contrast (Yes-No) 95% CI	P-Value
Age	Yes	41	51.22 (2.09)	7.76	1.8 to 13.72	0.01
	No	39	43.46 (2.14)			
% Body Fat	Yes	41	0.40 (0.01)	0.02	-0.02 to 0.06	0.26
	No	39	0.38 (0.01)			
Weight (lbs)	Yes	41	178.73 (6.1)	1.99	-15.4 to 19.38	0.82
	No	39	176.74 (6.25)			
Fat Mass (lbs)	Yes	41	73.38 (3.97)	5.09	-6.24 to 16.42	0.37
	No	39	68.29 (4.07)			
Fat free mass (lbs)	Yes	41	105.35 (3.63)	-3.1	-13.44 to 7.24	0.55
	No	39	108.45 (3.72)			
Bone density	Yes	41	1.21 (0.02)	-0.01	-0.06 to 0.05	0.83
	No	39	1.22 (0.02)			

Table 3 shows Comparisons of baseline ages and body composition measurements between subjects who complied with Time and those who did not for the 38 subjects in (treatment) Group A only. As was found with the combined groups, these data reveal that the compliant subjects were older (52.5 vs 43.3 yrs,  $P=0.04$ ) than non-compliant subjects. The compliant group also has significantly lower BMD ( $P=0.04$ ), as would be expected since BMD decreases with age—particularly among post-menopausal women. There are no statistically significant differences between the compliant and non-compliant subjects on any of the other body composition measurements (%fat, weight, fat mass, and fat-free mass).

Table 4 shows Comparisons of baseline ages and body composition between subjects who complied with Time and those who did not for the 42 subjects in (Placebo) Group P only. These data show that there were no significant differences between compliant and non-compliant subjects on age or %fat, weight, fat mass, and fat-free mass. It is worth noting that when ages are held constant, there is no difference between BMD levels confirming the assumption about the differences in BMD in Table 3.

**Table 3. Comparisons of Baseline Ages and Body Composition Measurements between Compliant and Non-Compliant Subjects in the (Treatment) Group A Only for Time.**

Outcome Measure	Compliance to Time	N	Mean (SEM)	Compliance Mean Difference	Mean Contrast (Yes-No) 95% CI	P-value
Age	Yes	19	52.53 (3.09)	9.26	0.39 to 18.13	0.04
	No	19	43.26 (3.09)			
% Body Fat	Yes	19	0.42 (0.02)	0.04	-0.01 to 0.09	0.14
	No	19	0.38 (0.02)			
Weight (lbs)	Yes	19	172.16 (9.3)	-8.41	-35.07 to 18.2	0.53
	No	19	180.57 (9.3)			
Fat (lbs)	Yes	19	74.75 (6.23)	4.64	-13.24 to 22.5	0.60
	No	19	70.11 (6.23)			
Fat free mass (lbs)	Yes	19	97.41 (4.57)	-13.0	-26.14 to 0.05	0.051
	No	19	110.46 (4.57)			
Bone density	Yes	19	1.17 (0.02)	-0.07	-0.14 to 0	0.04
	No	19	1.24 (0.02)			

**Table 4. Comparisons of Baseline Ages and Body Composition Measurements between Compliant and Non-Compliant Subjects in the (Placebo) Group P Only for Time.**

Outcome Measure	Compliance to Time	N	Mean (SEM)	Compliance Mean Difference	Mean Contrast (Yes-No) 95% CI	P-value
Age	Yes	22	50.09 (2.89)	6.44	-2.03 to 14.91	0.13
	No	20	43.65 (3.03)			
% Body Fat	Yes	22	0.39 (0.02)	0.01	-0.05 to 0.07	0.78
	No	20	0.38 (0.02)			
Weight (lbs)	Yes	22	184.41 (8.1)	11.3	-12.44 to 35.0	0.34
	No	20	173.11 (8.5)			
Fat mass (lbs)	Yes	22	72.2 (5.19)	5.63	-9.58 to 20.85	0.46
	No	20	66.57 (5.45)			
Fat free mass (lbs)	Yes	22	112.21 (5.37)	5.67	-10.07 to 21.4	0.47
	No	20	106.54 (5.64)			
Bone density	Yes	22	1.25 (0.03)	0.05	-0.03 to 0.13	0.2
	No	20	1.2 (0.03)			

Table 5 shows the comparisons of baseline ages and body composition measurements between subjects who complied with Amt and those who did not for a combined cohort group of active and placebo subjects. There were no statistically significant differences between the compliant and non-compliant subjects on any of these baseline measurements. As shown previously, when there no difference in average age, there are no differences in average BMD.

**Table 5. Comparisons of Baseline Ages and Body Composition Measurements between Compliant and Non-Compliant Subjects in a Combined Group of Active and Placebo Subjects for Amt.**

Outcome Measure	Compliance to Amt	N	Mean (SEM)	Compliance Mean Contrast (Yes-No) Diff	95% CI	P-Value
Age	Yes	57	48.47 (1.83)	3.6	-3.2 to 10.41	0.30
	No	23	44.87 (2.89)			
% Body Fat	Yes	57	0.39 (0.01)	0	-0.05 to 0.04	0.85
	No	23	0.39 (0.02)			
Weight (lbs)	Yes	57	179.71 (5.16)	6.78	-12.38 to 25.9	0.48
	No	23	172.93 (8.12)			
Fat (lbs)	Yes	57	71.48 (3.39)	2	-10.57 to 14.5	0.75
	No	23	69.48 (5.33)			
Fat free mass (lbs)	Yes	57	108.24 (3.07)	4.78	-6.61 to 16.17	0.41
	No	23	103.46 (4.83)			
Bone density	Yes	57	1.23 (0.02)	0.03	-0.03 to 0.09	0.34
	No	23	1.20 (0.02)			

Table 6 shows the comparisons of baseline ages and body composition between subjects who complied with Amt and those who did not for the (treatment) Group A only. There were no statistically significant differences between the compliant and non-compliant subjects on any of these baseline measurements. As shown previously, when there no difference in average age, there are no differences in average BMD.

**Table 6. Comparisons of Baseline Ages and Body Composition Measurements between Compliant and Non-Compliant Subjects in the (Treatment) Group A Only for Amt**

Outcome Measure	Compliance to Amt	N	Mean (SEM)	Compliance Mean Contrast (Yes-No) Difference	95% CI	P-value
Age	Yes	25	51.08 (2.71)	9.31	-0.09 to 18.71	0.05
	No	13	41.77 (3.76)			
Percent Body Fat	Yes	25	0.41 (0.02)	0.03	-0.03 to 0.08	0.32
	No	13	0.38 (0.02)			
Weight (lbs)	Yes	25	177.34 (8.15)	2.86	-25.39 to 31.1	0.84
	No	13	174.48 (11.3)			
Fat (lbs)	Yes	25	74.26 (5.43)	5.34	-13.48 to 24.1	0.57
	No	13	68.92 (7.53)			
Fat free mass (lbs)	Yes	25	103.09 (4.19)	-2.48	-17.02 to 12.0	0.73
	No	13	105.57 (5.82)			
Bone density	Yes	25	1.21 (0.02)	0.01	-0.06 to 0.09	0.72
	No	13	1.2 (0.03)			

Table 7 compares baseline ages and body composition measurements between subjects who complied with Amt and those who did not for the (placebo) Group P only. There were no statistically significant differences between the compliant and non-compliant subjects and, as shown previously, when there is no differences in age, there are no differences in BMD.

**Table 7. Comparisons of Baseline Ages and Body Composition Measurements between Compliant and Non-Compliant Subjects in the (Placebo) Group P Only for Amt.**

Outcome Measure	Compliance to Amt	N	Mean (SEM)	Compliance Mean Contrast (Yes-No) Diff	95% CI	P-value
Age	Yes	32	46.44 (2.46)	-2.46	-12.65 to 7.72	0.63
	No	10	48.9 (4.4)			
% Body Fat	Yes	32	0.37 (0.02)	-0.03	-0.1 to 0.03	0.32
	No	10	0.41 (0.03)			
Weight (lbs)	Yes	32	181.56 (6.75)	10.64	-17.3 to 38.59	0.45
	No	10	170.92 (12.07)			
Fat Mass (lbs)	Yes	32	69.3 (4.34)	-0.91	-18.87 to 17.0	0.92
	No	10	70.21 (7.76)			
Fat free mass (lbs)	Yes	32	112.26 (4.39)	11.55	-6.66 to 29.75	0.21
	No	10	100.71 (7.86)			
Bone density	Yes	32	1.23 (0.02)	0.04	-0.05 to 0.14	0.37
	No	10	1.19 (0.04)			

Analyses of the third compliance classification, "Both", are presented in Table 8 for the combined cohort group, Table 9 for the (treatment) Group A, and Table 10 for the (placebo) Group P. As shown in Table 8, the mean age of compliers (51.7 years) was significantly greater than the mean age of non-compliers (44.3 years),  $p=0.02$ . There were no significant differences between compliers and non-compliers on the baseline mean of any of the remaining 5 body composition variables.

**Table 8. Comparisons of Baseline Ages and Body Composition between Compliant and Non-Compliant Subjects in a Combined Cohort of Active and Placebo Subjects for Both measures of Compliance**

Outcome Measure	Compliance to Both	N	Mean (SEM)	Compliance Mean Contrast (Yes-No) Difference	95% CI	P-value
Age	Yes	34	51.71 (2.3)	7.42	1.37 to 13.47	0.02
	No	46	44.28 (1.98)			
% Body Fat	Yes	34	0.4 (0.01)	0.02	-0.02 to 0.06	0.26
	No	46	0.38 (0.01)			
Weight (lbs)	Yes	34	183.54 (6.65)	10.05	-7.39 to 27.5	0.25
	No	46	173.49 (5.71)			
Fat (lbs)	Yes	34	75.61 (4.33)	8.2	-3.17 to 19.56	0.16
	No	46	67.42 (3.72)			
Fat free mass (lbs)	Yes	34	107.93 (3.99)	1.86	-8.61 to 12.33	0.73
	No	46	106.07 (3.43)			
Bone density	Yes	34	1.22 (0.02)	0.01	-0.04 to 0.07	0.6
	No	46	1.21 (0.02)			

Table 9 reveals that the average percent body fat among compliers (44%) was significantly greater than the average (38%) among non-compliers ( $p=0.02$ ). There were no significant differences between compliers and non-compliers with regard to the baseline mean age or the remaining four body composition measurements.

**Table 9. Comparisons of Baseline Ages and Body Composition Measurements between Compliant and Non-Compliant Subjects for the (treatment) Group A Only for a Combination of both measures of Compliance: Time and Amt.**

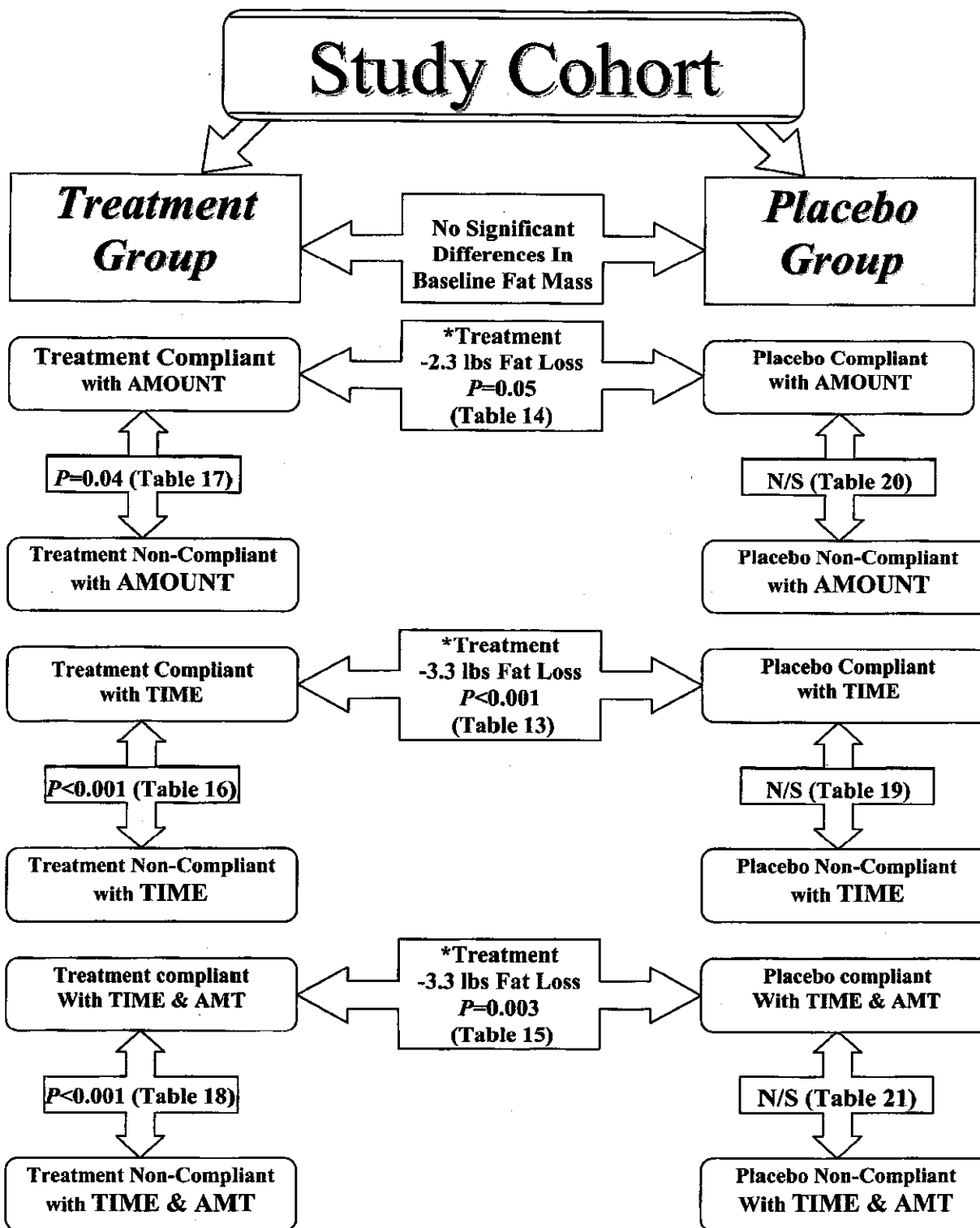
Outcome Measure	Compliance to Both	N	Mean (SEM)	Compliance Mean Contrast (Yes-No) Difference	95% CI	P-value
Age	Yes	16	53.44 (3.36)	9.57	0.61 to 18.53	0.04
	No	22	43.86 (2.87)			
% Body Fat	Yes	16	0.44 (0.02)	0.06	0.01 to 0.11	0.02
	No	22	0.38 (0.02)			
Weight (lbs)	Yes	16	178.38 (10.18)	3.47	-23.66 to 30.6	0.8
	No	22	174.9 (8.68)			
Fat (lbs)	Yes	16	79.57 (6.64)	12.34	-5.35 to 30.02	0.17
	No	22	67.24 (5.66)			
Fat free mass (lbs)	Yes	16	98.8 (5.13)	-8.86	-22.54 to 4.81	0.2
	No	22	107.67 (4.37)			
Bone density	Yes	16	1.19 (0.03)	-0.03	-0.11 to 0.04	0.34
	No	22	1.22 (0.02)			

The data in Table 10 reveal that there were no significant differences between compliers and non-compliers on age or any of the five body composition measurements.

**Table 10. Comparisons of Baseline Ages and Body Composition Measurements between Compliant and Non-Compliant Subjects for the (Placebo) Group P Only for a Combination of both measures of Compliance: Time and Amt.**

Outcome Measure	Compliance to Both	N	Mean (SEM)	Compliance Mean Contrast (Yes-No) Difference	95% CI	P-value
Age	Yes	18	50.17 (3.22)	5.5	-3.12 to 14.12	0.20
	No	24	44.67 (2.79)			
% Body Fat	Yes	18	0.38 (0.02)	-0.01	-0.07 to 0.05	0.72
	No	24	0.39 (0.02)			
Weight (lbs)	Yes	18	188.14 (8.86)	15.94	-7.75 to 39.63	0.18
	No	24	172.2 (7.67)			
Fat (lbs)	Yes	18	72.1 (5.76)	4.51	-10.88 to 19.9	0.56
	No	24	67.58 (4.99)			
Fat free mass (lbs)	Yes	18	116.04 (5.82)	11.43	-4.13 to 26.99	0.15
	No	24	104.61 (5.04)			
Bone density	Yes	18	1.26 (0.03)	0.06	-0.02 to 0.14	0.16
	No	24	1.2 (0.03)			

**Figure 1.** Comparisons of Changes in DEXA-Measured Fat Mass Between Treatment and Placebo Sub-groups Corrected for Compliance to Amount of Capsules (6/day), Time Taken (30 Minutes Prior to Eating), and Both (Amount & Time). Differences in Fat Mass (lbs) Expressed as Relative to Comparisons With Placebo or Non-compliant Sub-group. All reported weights are in lbs.



\* No statistically significant differences in baseline fat mass were found between treatment and placebo groups after classified as compliant or non-compliant.

Analyses of covariance models were applied to assess the significance of changes in the relation between outcome and treatment with compliance. The results, summarized in Table 11, show that the relation between outcome and treatment changed with compliance to Time for percent body fat ( $p=0.04$ ), weight ( $p<0.001$ ), and fat ( $p<0.001$ ), and that the relation between treatment and fat free mass, body composition index, and bone density did not change with compliance to Time. Table 11 also suggests that the relation between treatment group and any of the six outcomes did not vary significantly with compliance to Amt (because all of the interaction  $p$ -values for Amt are greater than 0.05).

Table 11. Interaction model summaries

Outcome Measure	Compliance	P-value <sup>1</sup>
Percent Body Fat <sup>2</sup>	Amt	0.36
	Time	0.04
Weight <sup>2</sup> (lbs)	Amt	0.81
	Time	<0.001
Fat <sup>2</sup> (lbs)	Amt	0.34
	Time	0.002
Fat Free Mass <sup>2</sup> (FFM) (lbs)	Amt	0.31
	Time	0.05
Body Composition Index <sup>3</sup> (lbs)	Amt	0.21
	Time	0.38
Bone Density <sup>2</sup>	Amt	0.87
	Time	0.48

<sup>1</sup>For the test of hypothesis of no interaction between outcome, treatment group and compliance.

<sup>2</sup>Change from visit 1 to 2, defined as value at visit 2 minus value at visit 1 (negative values indicate benefit)

<sup>3</sup>Defined as the change in FFM minus the change in fat (positive values indicate benefit).

As shown in Table 12 below, without correcting for compliance, there were no significant treatment effects for either Time or Amt on the outcome measures.

Table 12. Comparisons Between Treatment (Group A) and Placebo (Group P) Groups Before Correcting for Compliance

Outcome Measure	Group	N	Mean (SEM)	Compliance Mean Contrast (Yes-No) Difference	95% CI	P-value
% Body Fat <sup>1</sup>	A	38	0.02 (0.27)	-0.51	-1.24 to 0.23	0.18
	P	42	0.53 (0.25)			
Weight <sup>1</sup> (lbs)	A	38	0.55 (0.77)	-0.66	-2.77 to 1.45	0.53
	P	42	1.21 (0.73)			
Fat <sup>1</sup> (lbs)	A	38	0.16 (0.63)	-0.94	-2.67 to 0.78	0.28
	P	42	1.1 (0.6)			
Fat Free Mass <sup>1</sup> (lbs)	A	38	0.39 (0.52)	0.28	-1.15 to 1.71	0.7
	P	42	0.11 (0.5)			
Body Comp Index <sup>2</sup> (lbs)	A	38	0.23 (0.86)	1.22	-1.14 to 3.59	0.31
	P	42	-0.99 (0.82)			
Bone Density <sup>1</sup>	A	38	-0.59 (0.33)	-0.45	-1.34 to 0.45	0.32
	P	42	-0.14 (0.31)			

1. Change from visit 1 to visit 2, defined as value at visit 2 minus value at visit 1 (negative values indicate benefit).

2. Defined as the change in fat free mass minus the change in fat (positive values indicate benefit).

Restriction to subjects compliant to Time (Table 13) revealed a significant and beneficial mean decrease in percent body fat ( $p=0.007$ ), weight ( $p<0.001$ ) and fat ( $p<0.001$ ) in group A relative to group P and no significant difference between groups A and P with regard to mean changes in fat free mass, body composition index, and bone density ( $p>0.05$  for each of these).

**Table 13. Treatment (A) and Placebo (P) Group contrasts among subjects compliant with regard to Time**

Outcome Measure	Group	N	Mean (SEM)	Compliance Mean Contrast (Yes-No)		
				Difference	95% CI	P-value
% Body Fat <sup>1</sup>	A	19	-0.83 (0.34)	-1.31	-2.24 to -0.38	0.007
	P	22	0.49 (0.31)			
Weight <sup>1</sup> (lbs)	A	19	-2.87 (0.85)	-4.74	-7.07 to -2.4	<0.001
	P	22	1.87 (0.79)			
Fat <sup>1</sup> (lbs)	A	19	-2.49 (0.76)	-3.7	-5.79 to -1.61	<0.001
	P	22	1.21 (0.7)			
Fat Free Mass <sup>1</sup> (lbs)	A	19	-0.38 (0.73)	-1.04	-3.05 to 0.96	0.3
	P	22	0.66 (0.68)			
Body Comp Index <sup>2</sup> (lbs)	A	19	2.11 (1.22)	2.65	-0.71 to 6.02	0.12
	P	22	-0.55 (1.13)			
Bone Density <sup>1</sup>	A	19	-0.36 (0.46)	-0.12	-1.39 to 1.16	0.85
	P	22	-0.24 (0.43)			

1. Change from visit 1 to visit 2, defined as the value at visit 2 minus the value at visit 1 (negative values indicate benefit).

2. Defined as the change in fat free mass minus the change in fat (positive values indicate benefit).

As shown in Table 14, a comparison of subjects compliant to Amt revealed a significant and beneficial mean decrease in % body fat ( $p=0.05$ ) and fat in group A relative to group P ( $p=0.05$ ). There were no significant differences between groups with regard to mean changes in body weight ( $p=0.19$ ), fat free mass ( $p=0.63$ ), body composition index ( $p=0.09$ ), or bone density ( $p=0.47$ ).

**Table 14. Treatment (A) & Placebo (P) Group contrasts among subjects compliant with regard Amount.**

Outcome Measure	Group	N	Mean (SEM)	Compliance Mean Contrast (Yes-No)		
				Difference	95% CI	P-value
% Body Fat <sup>1</sup>	A	25	-0.23 (0.35)	-0.92	-1.85 to 0.01	0.053
	P	32	0.69 (0.31)			
Weight <sup>1</sup> (lbs)	A	25	-0.48 (0.96)	-1.69	-4.26 to 0.88	0.19
	P	32	1.21 (0.85)			
Fat <sup>1</sup> (lbs)	A	25	-0.76 (0.8)	-2.13	-4.26 to 0	0.05
	P	32	1.38 (0.7)			
Fat Free Mass <sup>1</sup> (lbs)	A	25	0.28 (0.68)	0.44	-1.36 to 2.25	0.63
	P	32	-0.16 (0.6)			
Body Comp Index <sup>2</sup> (lbs)	A	25	1.04 (1.12)	2.57	-0.43 to 5.57	0.09
	P	32	-1.54 (0.99)			
Bone Density <sup>1</sup>	A	25	-0.56 (0.35)	-0.34	-1.28 to 0.6	0.47
	P	32	-0.22 (0.31)			

1. Change from visit 1 to visit 2, defined as the value at visit 2 minus the value at visit 1 (negative values indicate benefit).

2. Defined as the change in fat free mass minus the change in fat (positive values indicate benefit).

A comparison of subjects compliant to Both (Table 15) revealed a significant benefit to group A for mean changes in % body fat ( $p=0.01$ ), weight ( $p<0.001$ ) and fat ( $p=0.003$ ). There was no significant difference between groups A and P with regard to change in FFM ( $p=0.33$ ), body composition index ( $p=0.15$ ) or bone density ( $p=0.38$ ).

**Table 15. Treatment (A) and Placebo (P) Group contrasts among subjects compliant with regard to both Time and Amount.**

Outcome Measure	Group	N	Mean (SEM)	Compliance Difference	Mean Contrast (Yes-No) 95% CI	P-value
% Body Fat <sup>1</sup>	A	16	-0.81 (0.37)	-1.36	-2.39 to -0.33	0.01
	P	18	0.54 (0.35)			
Weight <sup>1</sup> (lbs)	A	16	-2.75 (0.95)	-4.93	-7.59 to -2.28	<0.001
	P	18	2.18 (0.89)			
Fat <sup>1</sup> (lbs)	A	16	-2.47 (0.87)	-3.86	-6.29 to -1.44	0.003
	P	18	1.39 (0.82)			
Fat Free Mass <sup>1</sup> (FFM) (lbs)	A	16	-0.28 (0.79)	-1.07	-3.29 to 1.15	0.33
	P	18	0.79 (0.75)			
Body Comp Index <sup>2</sup> (lbs)	A	16	2.19 (1.37)	2.79	-1.03 to 6.62	0.15
	P	18	-0.60 (1.29)			
Bone Density <sup>1</sup>	A	16	-0.64 (0.49)	-0.6	-1.99 to 0.78	0.38
	P	18	-0.03 (0.47)			

1. Change from visit 1 to visit 2, defined as the value at visit 2 minus the value at visit 1 (negative values indicate benefit).
2. Defined as the change in fat free mass minus the change in fat (positive values indicate benefit).

Tables 16, 17 and 18 summarize mean contrasts within group A of compliers and non-compliers with regard to Time, Amt, and Both on each of the six outcomes. The same series was repeated for group P in Tables 19, 20 and 21. Within group A (Table 16), compliers to Time experienced a significant and beneficial reduction in percent body fat ( $p<0.001$ ), weight ( $p<0.001$ ), fat ( $p<0.001$ ), and a significant and beneficial increase in the mean body composition index ( $p=0.02$ ) relative to those who did not comply.

**Table 16. Contrasts on compliance to Time within group A.**

Outcome Measure	Compliance to Amt	N	Mean (SEM)	Compliance Difference	Mean Contrast (Yes-No) 95% CI	P-value
% Body Fat <sup>1</sup>	Yes	19	-0.83 (0.3)	-1.7	-2.55 to 0.85	<0.001
	No	19	0.87 (0.3)			
Weight <sup>1</sup> (lbs)	Yes	19	-2.87 (0.8)	-6.84	-9.14 to -4.55	<0.001
	No	19	3.97 (0.8)			
Fat <sup>1</sup> (lbs)	Yes	19	-2.49 (0.64)	-5.29	-7.14 to -3.45	<0.001
	No	19	2.81 (0.64)			
Fat Free Mass <sup>1</sup> (lbs)	Yes	19	-0.38 (0.67)	-1.55	-3.46 to 0.37	0.11
	No	19	1.17 (0.67)			
Body Comp Index <sup>2</sup> (lbs)	Yes	19	2.11 (1.04)	3.75	0.77 to 6.73	0.02
	No	19	-1.64 (1.04)			
Bone Density <sup>3</sup>	Yes	19	-0.36 (0.51)	0.47	-0.99 to 1.92	0.52
	No	19	-0.83 (0.51)			

1. Change from visit 1 to visit 2, defined as the value at visit 2 minus the value at visit 1 (negative values indicate benefit).
2. Defined as the change in fat free mass minus the change in fat (positive values indicate benefit).

Within group A (Table 17), compliers to Amt experienced a significant and beneficial reduction in mean fat ( $p=0.04$ ) relative to those who did not comply.

**Table 17. Contrasts on compliance to Amt within group A**

Outcome Measure	Compliance to Amt	N	Mean (SEM)	Compliance Mean Contrast (Yes-No) Difference	95% CI	P-value
% Body Fat <sup>1</sup>	Yes	25	-0.23 (0.3)	-0.73	-1.78 to 0.33	0.17
	No	13	0.5 (0.42)			
Weight <sup>1</sup> (lbs)	Yes	25	-0.48 (0.95)	-3.01	-6.29 to 0.27	0.07
	No	13	2.53 (1.31)			
Fat <sup>1</sup> (lbs)	Yes	25	-0.76 (0.74)	-2.68	-5.23 to -0.12	0.04
	No	13	1.92 (1.02)			
Fat Free Mass <sup>1</sup> (lbs)	Yes	25	0.28 (0.6)	-0.33	-2.42 to 1.76	0.75
	No	13	0.61 (0.84)			
Body Comp Index <sup>2</sup> (lbs)	Yes	25	1.04 (0.96)	2.35	-0.97 to 5.66	0.16
	No	13	-1.31 (1.33)			
Bone Density <sup>3</sup>	Yes	25	-0.56 (0.45)	0.09	-1.45 to 1.64	0.9
	No	13	-0.65 (0.62)			

1. Change from visit 1 to visit 2, defined as the value at visit 2 minus the value at visit 1 (negative values indicate benefit).
2. Defined as the change in fat free mass minus the change in fat (positive values indicate benefit).

Within group A (Table 18) compliers to Both experienced a significant and beneficial reduction in percent body fat ( $p=0.003$ ), weight ( $p<0.001$ ), fat ( $p<0.001$ ) and a significant and beneficial increase in the mean body composition index ( $p=0.03$ ) as compared to those who did not comply. There were no significant difference between compliers and non-compliers on mean changes in fat free mass ( $p=0.24$ ), or bone density ( $p=0.92$ ).

**Table 18. Contrasts on compliance to both Time and Amt within group A.**

Outcome Measure	Compliance to Both	N	Mean (SEM)	Compliance Mean Contrast (Yes-No) Difference	95% CI	P-value
% Body Fat <sup>2</sup>	Yes	16	-0.81 (0.34)	-1.44	-2.36 to -0.52	0.003
	No	22	0.63 (0.29)			
Weight <sup>2</sup> (lbs)	Yes	16	-2.75 (1)	-5.7	-8.38 to -3.03	<0.001
	No	22	2.95 (0.86)			
Fat <sup>2</sup> (lbs)	Yes	16	-2.47 (0.79)	-4.54	-6.65 to -2.44	<0.001
	No	22	2.07 (0.67)			
Fat Free Mass <sup>2</sup> (lbs)	Yes	16	-0.28 (0.74)	-1.16	-3.13 to 0.81	0.24
	No	22	0.88 (0.63)			
Body Comp Index <sup>3</sup> (lbs)	Yes	16	2.19 (1.15)	3.38	0.31 to 6.45	0.03
	No	22	-1.19 (0.98)			
Bone Density <sup>2</sup>	Yes	16	-0.64 (0.56)	-0.08	-1.56 to 1.41	0.92
	No	22	-0.56 (0.47)			

1. Change from visit 1 to visit 2, defined as the value at visit 2 minus the value at visit 1 (negative values indicate benefit).
2. Defined as the change in fat free mass minus the change in fat (positive values indicate benefit).

Analyses of Placebo Group are shown in Tables 19, 20, and 21. No significant differences between compliers and non-compliers were found in Time, Amt, or Both on changes in any of the outcomes.

**Table 19. Contrasts on compliance to Time within group P.**

Outcome Measure	Compliance to Time	N	Mean (SEM)	Compliance Difference	Mean Contrast (Yes-No) 95% CI	P-value
% Body Fat <sup>1</sup>	Yes	22	0.49 (0.38)	-0.09	-1.19 to 1.02	0.87
	No	20	0.57 (0.4)			
Weight <sup>1</sup> (lbs)	Yes	22	1.87 (0.98)	1.37	-1.5 to 4.25	0.34
	No	20	0.5 (1.03)			
Fat <sup>1</sup> (lbs)	Yes	22	1.21 (0.84)	0.22	-2.23 to 2.67	0.86
	No	20	0.99 (0.88)			
Fat Free Mass <sup>1</sup> (lbs)	Yes	22	0.66 (0.73)	1.15	-0.97 to 3.28	0.28
	No	20	-0.49 (0.76)			
Body Comp Index <sup>2</sup> (lbs)	Yes	22	-0.55 (1.22)	0.93	-2.64 to 4.5	0.6
	No	20	-1.48 (1.28)			
Bone Density <sup>1</sup>	Yes	22	-0.24 (0.39)	-0.21	-1.36 to 0.94	0.72
	No	20	-0.04 (0.41)			

1. Change from visit 1 to visit 2, defined as the value at visit 2 minus the value at visit 1 (negative values indicate benefit).
2. Defined as the change in fat free mass minus the change in fat (positive values indicate benefit).

**Table 20. Contrasts on compliance to Amt within group P.**

Outcome Measure	Compliance to Capsules	N	Mean (SEM)	Compliance Difference	Mean Contrast (Yes-No) 95% CI	P-value
% Body Fat <sup>1</sup>	Yes	32	0.69 (0.31)	0.69	-0.59 to 1.96	0.28
	No	10	0 (0.55)			
Weight <sup>1</sup> (lbs)	Yes	32	1.21 (0.82)	-0.01	-3.42 to 3.4	1.00
	No	10	1.22 (1.47)			
Fat <sup>1</sup> (lbs)	Yes	32	1.38 (0.69)	1.14	-1.71 to 3.99	0.42
	No	10	0.23 (1.23)			
Fat Free Mass <sup>1</sup> (lbs)	Yes	32	-0.16 (0.6)	-1.15	-3.65 to 1.35	0.36
	No	10	0.99 (1.08)			
Body Comp Index <sup>2</sup> (lbs)	Yes	32	-1.54 (1)	-2.3	-6.43 to 1.84	0.27
	No	10	0.76 (1.79)			
Bone Density <sup>1</sup>	Yes	32	-0.22 (0.33)	-0.32	-1.67 to 1.03	0.64
	No	10	0.1 (0.58)			

1. Change from visit 1 to visit 2, defined as the value at visit 2 minus the value at visit 1 (negative values indicate benefit).
2. Defined as the change in fat free mass minus the change in fat (positive values indicate benefit).

**Table 21. Contrasts on compliance to both Time and Amt within group P.**

Outcome Measure	Compliance to Both	N	Mean (SEM)	Compliance Mean Contrast (Yes-No) Difference	95% CI	P-value
% Body Fat <sup>1</sup>	Yes	18	0.54 (0.42)	0.03	-1.09 to 1.14	0.96
	No	24	0.52 (0.36)			
Weight <sup>1</sup> (lbs)	Yes	18	2.18 (1.08)	1.7	-1.19 to 4.58	0.24
	No	24	0.49 (0.93)			
Fat <sup>1</sup> (lbs)	Yes	18	1.39 (0.92)	0.51	-1.96 to 2.97	0.68
	No	24	0.89 (0.8)			
Fat Free Mass <sup>1</sup> (lbs)	Yes	18	0.79 (0.8)	1.19	-0.95 to 3.33	0.27
	No	24	-0.4 (0.69)			
Body Comp Index <sup>2</sup> (lbs)	Yes	18	-0.6 (1.35)	0.68	-2.93 to 4.29	0.7
	No	24	-1.28 (1.17)			
Bone Density <sup>1</sup>	Yes	18	-0.03 (0.43)	0.19	-0.97 to 1.35	0.74
	No	24	-0.23 (0.38)			

1. Change from visit 1 to visit 2, defined as the value at visit 2 minus the value at visit 1 (negative values indicate benefit).

2. Defined as the change in fat free mass minus the change in fat (positive values indicate benefit).

We were concerned that baseline differences between compliers and non-compliers to Time in group A (Table 3) may have influenced mean comparisons between and within groups on changes from baseline, summarized in Tables 13 through 21. To address this, we re-analyzed all between-group and within-group contrasts on mean changes from baseline with adjustment for age (results not shown in any table).

The age-adjusted between-group contrasts were the same as the unadjusted contrasts (Tables 13 through 15) with regard to direction and statistical significance, with the single exception that after adjustment for age the group contrast on the mean change in fat among subjects compliant to capsules (Table 14) became non-significant ( $p=0.11$ ); the age-adjusted mean changes were  $-0.50$  in group A and  $1.18$  in group P.

The age-adjusted within-group contrasts were the same as the unadjusted contrasts (Tables 16 through 21) with regard to direction and statistical significance, with the exceptions that 1) the contrast between compliers and non-compliers to Time on the mean change in the body composition index in group A (Table 16) became non-significant ( $p=0.054$ ) after adjustment for age; the age-adjusted mean changes were  $1.77$  in group A and  $-1.31$  in group P, 2) the contrast between compliers and non-compliers to capsules on the mean change in fat in group A (Table 17) became non-significant ( $p=0.14$ ) after adjustment for age; the age-adjusted mean changes were  $-0.50$  in group A and  $1.43$  in group P, and 3) the contrast between compliers to both Time and capsules on the mean change in the body composition index in group A (Table 18) became non-significant ( $p=0.11$ ) after adjustment for age; the age-adjusted mean changes were  $1.76$  in group A and  $-0.88$  in group P.

**Blood Chemistries.** Table 22 shows comparisons of the baseline scores and baseline-ending changes for 42 blood chemistries for Groups A and P. P-values are also shown for between-group comparisons on each of the chemistries listed. As these data reveal, there were three statistically significant differences between the groups at baseline (AST [SGOT], Eosinophils, and Potassium). However, none of these differences were found in the baseline-ending change scores, suggesting the differences at baseline may have been attributable to chance. Although there were no differences between Group A and Placebo at baseline in Total Cholesterol (TC) and LDL Cholesterol (LDL), a comparison of cholesterol changes occurring in the two groups revealed a significantly greater reduction ( $-13.9$ ) in total cholesterol ( $P<.008$ ) and in LDL cholesterol ( $-13.7$   $P<.005$ ) in Group A as compared to the Placebo group. Both groups were further stratified into 3 sub-groups using baseline total cholesterol levels of (High= $\geq 200$ ; Acceptable= $151-199$ , Low= $\leq 151$ ). In Group A, subjects with "high" cholesterol had a statistically significant reduction in both total and LDL cholesterol. Those with "acceptable" levels remained unchanged and those with "low" levels increased their cholesterol levels, although the latter failed to reach statistical significance. There were no significant reductions in cholesterol or LDL levels in the "high cholesterol" placebo group.

Table 22. Comparisons Between Mean Baseline and Ending Scores on 37 Blood Chemistries

	Baseline		Active vs Pla	Change Scores		Active vs Pla
	Active	Placebo	P-values	Active	Placebo	P-values
ALBUMIN	4.2	4.3	0.37	-0.1	-0.1	0.27
ALBUMIN/GLOBULIN RATIO	1.5	1.5	0.34	-0.1	-0.1	0.29
ALKALINE PHOSPHATASE	74.2	74.7	0.93	-2.4	0.3	0.34
ALT (SGPT)	25.3	18.6	0.11	-2.0	0.0	0.59
AST (SGOT)	22.2	18.0	0.02	-0.5	-0.9	0.81
BASOPHILS	0.5	0.6	0.54	0.0	-0.1	0.28
BASOPHILS, ABSOLUTE	35.4	38.9	0.59	-0.9	-8.0	0.24
BILIRUBIN, TOTAL	0.6	0.6	0.74	1.3	-0.1	0.31
BUN/CREATININE RATIO	14.6	15.5	0.35	1.7	0.6	0.32
CALCIUM	9.4	9.4	0.97	-0.4	-0.1	0.13
CARBON DIOXIDE	24.2	24.4	0.61	-0.7	0.1	0.23
CHLORIDE	104.8	104.7	0.77	-2.6	-0.3	0.26
CREATININE	0.9	0.9	0.65	-0.05	-0.02	0.27
C-reactive Protein (CRP)	7.0	3.8	0.17	-1.0	0.40	0.65
EOSINOPHILS	2.2	3.7	0.04	-0.1	0.0	0.67
EOSINOPHILS, ABSOLUTE	144.1	252.3	0.06	-7.4	3.4	0.59
GLOBULIN	2.9	2.8	0.54	0.1	0.1	0.83
GLUCOSE	95.5	96.8	0.82	-1.6	2.1	0.35
HEMATOCRIT	40.9	41.0	0.86	-0.6	1.3	0.17
HEMOGLOBIN	13.6	13.7	0.74	-0.1	0.1	0.20
LYMPHOCYTES	33.8	31.7	0.26	-2.5	-1.5	0.58
LYMPHOCYTES, ABSOLUTE	2105.7	2045.0	0.66	-79.0	-92.7	0.91
MCH	30.3	30.2	0.82	-0.1	0.0	0.46
MCHC	33.2	33.3	0.54	-0.3	-0.4	0.94
MCV	90.9	90.6	0.76	-0.9	-2.0	0.48
MONOCYTES	6.4	6.0	0.43	-0.1	-0.1	0.97
MONOCYTES, ABSOLUTE	415.3	390.3	0.54	9.0	5.1	0.90
NEUTROPHILS	57.0	57.9	0.67	0.8	2.1	0.54
NEUTROPHILS, ABSOLUTE	3746.1	3744.7	1.00	201.4	343.3	0.57
PLATELET COUNT	271.1	259.3	0.36	115.6	0.8	0.31
POTASSIUM	4.6	4.4	0.02	-0.2	0.0	0.06
PROTEIN, TOTAL	7.1	7.1	0.93	-0.1	0.0	0.44
RDW	13.6	13.5	0.69	4.5	5.1	0.93
RED BLOOD CELL COUNT	4.5	4.5	0.61	0.2	0.0	0.43
SODIUM	140.5	140.8	0.40	-0.3	-0.7	0.46
TSH	2.0	2.0	0.85	0.3	-0.1	0.46
UREA NITROGEN (BUN)	13.2	14.3	0.21	0.7	0.4	0.76
WHITE BLOOD CELL COUNT	6.4	6.5	0.94	0.2	0.2	0.73
TOTAL CHOLESTEROL	197.8	194.5	0.79	-7.9	6.0	0.008
TOTAL/HDL RATIO	3.8	3.9	0.53	-0.2	0.0	0.28
HDL CHOLESTEROL	56.2	54.5	0.60	-0.6	1.7	0.35
LDL CHOLESTEROL	118.7	114.9	0.69	-8.7	5.0	0.005
TRIGLYCERIDES	114.6	124.4	0.37	7.5	-2.6	0.28

## DISCUSSION

This study was designed as a PCT primarily to provide information to aid healthcare providers in deciding whether or not this dietary supplement can provide support for weight loss interventions. However, as opposed to using only changes in scale weight as the outcome measure as used in previous studies, this study used DEXA-derived changes in body composition as the outcome measure. A true measure of the safety and efficacy of a weight loss intervention should, in our view, include a measure of how much of the weight lost is excess body fat and how much is a depletion of lean or FFM. Our use of the Body Composition Improvement index was based on this consideration.

No statistically significant differences were found between the treatment and placebo groups on mean: age, percent body fat, scale weight, fat mass, fat-free mass and bone density validating the effectiveness of the randomization procedure to produce two statistically equivalent groups.

At the conclusion of the study, completion of the anonymous questionnaire regarding product usage allowed for collection of data under conditions that would maximize candor. The subsequent signing of the questionnaire by 95% (79 of 83 subjects) of the participants and the post-study telephone calls allowed for classification of participants into two sub-groups: those who complied with the product usage instructions and those who did not. Compliance was also based on three compliance categories: the time capsules were taken prior to eating (Time), the number of capsules taken (Amt) and both Time and Amt (Both). Once these classifications were made, a comparison of the three sub-groups within the treatment group revealed that subjects were evenly distributed between compliant and non-compliant categories since there were no statistically significant differences between the percentage of subjects in each of these three compliance categories. Furthermore, there were no statistically significant differences in the percentage of subjects in each of the three sub-groups when comparisons were made between the PLA and TRT sub-groups. The statistically significant reduction in bone density among compliers within the TRT group ( $r = -0.37$ ) appears attributable to a significant negative correlation between age and bone density in the TRT group. After classifying compliant and non compliant participants, compliers to Time, Amt or Both did not differ significantly from non-compliers with regard to the baseline mean percent body fat, weight, fat, fat free mass and bone density.

A comparison of compliant and non-compliant subjects within the treatment group revealed significant reductions in mean percent body fat, weight, and fat mass in all three compliant categories (Time, Amt and Both). These findings provide considerable support for product efficacy by demonstrating that the more of the product participants consumed, the better their results. Additionally, the more closely they complied with the requirement to take the product 30 minutes before eating, the better the results. One could argue that these differences between the compliant and non-compliant participants were a reflection of differential motivation levels among participants who made other diet changes in their lifestyles instead of differential effects of the product. However, if this was the case, a comparison of compliant and non-compliant subjects in the PLA would also reveal greater losses of body fat by the compliant as compared to non-compliant subjects. As these comparisons reveal, this was not the case—there were no statistically significant reductions in body fat in the compliant, as compared to non-compliant, sub-groups in the PLA group all but ruling out the motivational hypotheses. Thus, in addition to the significantly greater fat losses in the compliant TRT group as compared to the compliant PLA group, these within-group Consistent with treatment group by compliance interactions, restriction to subjects who complied to Time or to both Amt and Time revealed significant and beneficial reductions in the in group A relative to group P. Analyses within groups revealed a consistent and significant reduction in mean percent body fat, weight, and fat in compliers to Time and to both Time and Amt in group A, but not in group P. The within-group patterns suggest that the between-group contrasts, showing a benefit to group A, are consistent with the hypothesis that taking this supplement as prescribed will cause a reduction in body fat and weight.

Since no diet/exercise recommendations were provided, participants were free to follow any diet/exercise plan of their own choosing. One could make an argument that participants in a weight loss clinical trial who are willing to expend the time and energy to participate are people who are motivated to lose weight or they wouldn't participate and that this motivation would include following a diet/exercise of their own choosing. Conversely, an argument could also be advanced that people believing that they may have received an efficacious weight loss supplement, would make no alterations in diet and exercise relying, instead, on the supplement to achieve their weight loss goals. In either case, what the data do show is that the differences between the treatment and placebo groups suggest that the supplement provided the benefits whether or not they participated an diet/exercise plan of their own choosing.

Since this study was a PCT and not an explanatory study, we cannot conclude that the loss of body fat in the treatment group was the result of a reduced caloric intake. However, it is likely that subjects in the treatment

group most likely did alter their caloric intakes because of the product's high viscosity and a resultant swelling in the stomach resulting in increased satiety and feelings of "fullness" when taken 30 minutes before eating. Thus, the findings are consistent with the FDA's 2004 Working Group's conclusion reported in the May-June 2004 edition of *FDA Consumer*:

"Our report concludes that there is no substitute for the simple formula, 'calories in must equal calories out' in order to control weight. We're going back to basics, designing a comprehensive effort to attack obesity through an aggressive, science-based, consumer-friendly program with the simple message that Calories Count."

The weight loss found in this study was somewhat less than the over-placebo losses, adjusted to 60-days, that has been reported in other studies: -3.1 lbs, -5.7lbs, -7.0 lbs, -7.0 lbs<sup>14-17, respectively</sup>. However, none of these studies appear to have been conducted over the holiday season when high-risk challenges abound making it the most difficult time of the year to lose weight<sup>18-20</sup>. Even under experimental conditions with considerable experimental intervention, a study examining the relationship between self-monitoring and weight loss/gain during the high-risk holiday season concluded:

"...the holidays demonstrated their high risk for weight controllers by producing substantial decrements in self-monitoring and concomitantly poorer weight control when compared with non-holiday weeks....The holidays clearly established their potential to challenge even highly experienced weight controllers. . These findings suggest that the impact of the holidays could dampen momentum for many weight controllers, leading to major lapses and perhaps premature termination of treatment".<sup>21</sup>

The impact of the holiday season combined with the free-living conditions of minimal intervention employed in this study could well have accounted for the somewhat reduced weight loss found in the compliant group in this study as compared to previous studies. Furthermore, none of these studies reported changes in body composition, specifically, body fat. Therefore, some of the weight loss in the previous studies may have been attributed to fluid depletion.

**Compliance.** Poor patient compliance with, or adherence to, medical treatment plans and research protocols continues to undermine treatment benefits as well as the conduct and interpretation of weight loss studies. In spite of a plethora of studies on the safety and efficacy of medications, there are few rigorous trials demonstrating successful adherence interventions. For example, in their 2002 review of 6,568 citations (including 101 review articles) the reviewers concluded that in spite the fact that

"...effective ways to help people follow medical treatments could have far larger effects on health care than any individual treatment...the literature concerning interventions to improve adherence with medications remains surprisingly weak....current methods of improving medication adherence for chronic health problems are mostly complex, labor-intensive, and not predictably effective. The full benefits of medications cannot be realized at currently achievable levels of adherence..."<sup>22</sup>

Another review of 38 studies testing 58 different interventions and containing data on 15,519 patients designed to improve adherence to blood pressure-lowering medications concluded that:

"Simplifying dosing regimens increased adherence in 7 of 9 studies, with a relative increase in adherence of 8% to 19.6%. Motivational strategies were partly successful in 10 of 24 studies with generally small increases in adherence up to a maximum of 23%. Complex interventions comparing more than 1 technique increased adherence in 8 of 18 studies, ranging from 5% to a maximum of 41%. Patient education alone seemed largely unsuccessful."<sup>23</sup>

Other reviews have concluded that "Low adherence to prescribed medical regimens is a ubiquitous problem. Typical adherence rates are about 50% for medications and are much lower for lifestyle prescriptions and other more behaviorally demanding regimens."<sup>24</sup> These reviewers also report that patients substantially overestimate their actual adherence which is difficult to study and is poorly documented. "Even the most effective interventions did not lead to large improvements in adherence and treatment outcomes"<sup>25</sup> the reviewers conclude. Thus, even when adherence interventions are effective, they do not necessarily result in significant improvements in treatment outcomes. This would lead one to believe that either the treatment regimen was flawed or that the measures of compliance were flawed. It is our view that the latter is often the case.

These reviews concur that "Adherence can be increased with repeated telephone calls, on-line monitoring, frequent visits to the research center, completion of detailed tracking logs, and other motivation strategies and complex interventions".<sup>26</sup> However, even when multifaceted and complex compliance interventions are effective, they pose major challenges for the interpretation and generalization of the findings. Complex and multifaceted interventions created in a study environments often bear little resemblance to the free-living environments in which the products are most likely to be used. Thus, unless users can create the same conditions that were created in the experimental design, an effective intervention under these artificial conditions may have little relevance to the real world in which the products will be used.<sup>27-28</sup>

Since PCTs are designed to create conditions under which the product will be used, this study was conducted under conditions similar to those under which the product was most likely to be taken. In fact, this study was conducted over the holiday season when dieters face the greatest challenges and are least likely to adhere to weight loss regimens. Thus, it is conceivable that the amounts of body fat lost in this study would be even greater under less challenging conditions.

The results of this study also underscore the need to measure and correct for compliance. In fact, these data raise an important question about how many studies with apparently minimal or no efficacy were, in fact, efficacious, but the failure to correct for compliance obscured their actual efficacy. Past studies have repeatedly shown that study outcomes can be changed dramatically when appropriate compliance procedures are adopted. For example, in one of the previous studies cited above<sup>21</sup>, the researchers divided the study cohort into quartile groups on the basis of compliance with self-monitoring indexes. As in this study, there were no statistically significant differences in baseline measures between any of the four quartiles. The average weight loss over the 10-week study period for the entire cohort was 1.0 lbs. However, when comparing the compliance quartiles, the only quartile that achieved any weight loss was the upper high-compliance quartile. Interestingly, the high-compliance quartile lost an average of ~6.5 lbs, while the low-compliant quartile gained 6.5 lbs—a 13 lb difference between the high and low compliant groups. The data also suggest the need to emphasize to users of this product that it must be taken as directed to achieve the results found in this study.

**Fat vs Weight Loss.** As reported throughout this study, the principal outcome measure in this study was a reduction in body fat as opposed to scale weight. Two recent articles underscore the importance of using fat, as opposed to weight, losses, as an outcome measure. In the first article<sup>29</sup> Dr. George Bray, one of the world's most experienced obesity researchers and author of the Body Mass Index (BMI), reviews the "Medical consequences of obesity" and concludes:

"Obesity is an epidemic disease that threatens to inundate health care resources by increasing the incidence of diabetes, heart disease, hypertension, and cancer. These effects of obesity result from two factors: the increased mass of adipose tissue and the increased secretion of pathogenetic products from enlarged fat cells. This concept of the pathogenesis of obesity as a disease allows an easy division of disadvantages of obesity into those produced by the mass of fat and those produced by the metabolic effects of fat cells. In the former category are the social disabilities resulting from the stigma associated with obesity, sleep apnea that results in part from increased parapharyngeal fat deposits, and osteoarthritis resulting from the wear and tear on joints from carrying an increased mass of fat. The second category includes the metabolic factors associated with distant effects of products released from enlarged fat cells. The insulin-resistant state that is so common in obesity probably reflects the effects of increased release of fatty acids from fat cells that are then stored in the liver or muscle. When the secretory capacity of the pancreas is overwhelmed by battling insulin resistance, diabetes develops. The strong association of increased fat, especially visceral fat, with diabetes makes this consequence particularly ominous for health care costs. The release of cytokines, particularly IL-6, from the fat cell may stimulate the proinflammatory state that characterizes obesity. The increased secretion of prothrombin activator inhibitor-1 from fat cells may play a role in the procoagulant state of obesity and, along with changes in endothelial function, may be responsible for the increased risk of cardiovascular disease and hypertension. For cancer, the production of estrogens by the enlarged stromal mass plays a role in the risk for breast cancer. Increased cytokine release may play a role in other forms of proliferative growth. The combined effect of these pathogenetic consequences of increased fat stores is an increased risk of shortened life expectancy."<sup>29</sup>

In a second article in the *New England Journal of Medicine*<sup>30</sup> the researchers raise doubts about the value of simply removing body fat through liposuction, as opposed to creating a negative energy balance which appears to have happened in this study. As these researchers concluded:

"Our data show that the aspiration of large amounts of subcutaneous abdominal adipose tissue resulted in a considerable decrease in body weight, waist circumference, and plasma leptin concentrations but did not have a significant effect on insulin sensitivity in skeletal muscle (assessed as the stimulation of glucose uptake), in the liver (assessed as the suppression of glucose production), or adipose tissue (assessed as the suppression of lipolysis). In addition, liposuction had no significant effects on other risk factors for coronary heart disease, including blood pressure; fasting plasma glucose, insulin, and lipid concentrations; and concentrations of plasma markers of inflammation and insulin resistance (C-reactive protein, tumor necrosis factor, interleukin-6, and adiponectin).

The results of the present study suggest that abdominal liposuction should not, by itself, be considered a clinical therapy for obesity. Aspiration of large amounts of subcutaneous abdominal fat in women with abdominal obesity may have cosmetic benefits, but the procedure does not significantly improve insulin sensitivity in the liver, skeletal muscle, or adipose tissue; serum concentrations of markers of inflammation; or other risk factors for coronary heart disease. These findings offer important insights into the mechanisms responsible for the metabolic benefits observed with moderate diet-induced weight loss, which decreases hepatic and muscle fat content, fat-cell size, visceral fat mass, and circulating concentrations of proinflammatory cytokines. The effects of a negative energy balance on specific endogenous triglyceride depots and inflammation, which are not altered by liposuction, may be necessary to achieve many of the clinical benefits of therapy for obesity."<sup>30</sup>

**Long-term Potential.** As compared to many drug and nutritional supplement protocols, weight loss protocols can provide data that can be used to predict long-term effects if followed as prescribed in the study. For example, in studies on the lowering of cholesterol, almost all of the reduction of serum cholesterol levels occurs within a 60-90 day time period and further reductions are often small and statistically insignificant. This is not the case in weight loss studies where, if the study participants continue to follow the regimen in the study, further reductions in weight or body fat could continue until the participant reaches an appropriate goal weight. For example, in this study, free-living subjects without a prescribed exercise and diet plan who used the supplement as directed over a 60-day study period during the holiday season achieved a -3.86 lb over-placebo loss of fat (Table 15)—an important change in its own right since even losing modest weight is "...one of the most important public health messages to get out to people," says Dr. Judith Fradkin, diabetes endocrinology head at the National Institute of Diabetes and Digestive and Kidney Diseases. "The goal should be to become healthy, not become a fashion model. If you move in the right direction even a little bit, that can make a big difference in health."<sup>31</sup> Not only is this a highly significant finding ( $P=0.003$ ), but if continued for an additional 60 days could translate into a loss of body fat of 7.7 lbs, a 11.6 lb loss over six-months, and 23.2 lb fat loss over a year. In fact, one could argue that fat losses over the next 60-day non-holiday and typical "dieting season" from January to March could be even greater. Of course, these predictions are pure speculation and our data cannot attest to the likelihood of users following the product usage regimens of this study for extended time periods. Nonetheless, the potential profound effects these reductions of body fat could have for the obesity epidemic underscores the need for longer term studies using the supplement in conjunction with a prescribed diet and exercise plan.

## CONCLUSIONS

This study used a randomized double-blinded placebo-controlled protocol, corrected for compliance, to evaluate the safety and efficacy of taking 3 grams (1 gram, three times a day, 30 minutes before eating) of *Propol*<sup>™</sup>, a highly viscous glucomannan supplement. No significant adverse effects were reported by subjects in the treatment or placebo group. Nor were any adverse changes found in the 42 blood chemistries that were measured at baseline and at the conclusion of this study. The data revealed that when taken as directed, the supplement led to an reduction in Total and LDL cholesterol and facilitated a loss of excess body fat without any concomitant loss of lean mass or bone density. Highly significant increased fat losses were also found when comparing sub-groups of compliant subjects in the treatment program with compliant subjects in the placebo group. Additionally, within the treatment group, compliant treatment subjects lost significantly more fat than non-compliant subjects while within the placebo group, there were no differences in fat loss between compliant and non-compliant subjects. While previous studies have shown similar scale weight losses, the weight lost in this study was almost entirely excess body fat without any decrement in fat-free mass and bone density often associated with weight loss. It is also worth noting that these positive changes in cholesterol and fat losses found in this study occurred during the holiday season (Nov-Jan)—the most difficult time of the year to achieve these changes. The study also revealed the importance of measuring and correcting for compliance in weight

loss studies and the validity of a technique using a post-study anonymous questionnaire to improve the evaluation of subject compliance. It is our conclusion that taking this dietary supplement as directed can be a useful and safe adjunct to a weight loss program.

#### Author Contributions:

Study Concept and Design: Kaats, Keith, Preuss, Michalek

Acquisition of Data: Keith, Dapilmoto.

Drafting of manuscript: Kaats, Keith, Preuss, Michalek

Critical revision of the manuscript for important intellectual content: Kaats, Keith, Preuss, Michalek, Bastarrachea and McDaniel.

Statistical expertise: Michalek

Obtaining funding: Kaats

Administrative, technical or material support: Kaats, Keith, Dapilmoto

Supervision: Kaats, Keith, Preuss, Michalek

**Funding/Support:** Natural Alternatives International, Inc.

**Role of Sponsors:** NAI participated in the study concept and design, but at no time had access to the data, participate in statistical analyses, nor participate in the preparation or critical review of the manuscript.

**Disclaimer:** The opinions or assertions contained in this article are those of the authors and are not to be construed as reflecting the views of the institutions in which the authors are employed.

#### REFERENCES:

1. Public Law 103-417. 103<sup>rd</sup> Congress, 2<sup>nd</sup> session. October 25, 1994. *The Dietary Supplement Health and Education Act (DSHEA) of 1994*.
2. Office of Dietary Supplements. 1998. Merging Quality Science with Supplement Research: A Strategic Plan for the Office of Dietary Supplements. NIH Publ. No. 99-4356. Available at <http://ods.od.nih.gov/showpage.aspx?pageid=69#plan>.
3. *Promoting Quality Science in Dietary Supplement Research, Education, and Communication: A Strategic Plan for the Office of Dietary Supplements: 2004-2009*. The Office of Dietary Supplements, Office of the Director National Institutes of Health, January 28, 2004. Available at <http://ods.od.nih.gov/pubs/SP10B.Web.pdf>.
4. Manson JE, Colditz GA, Stampfer MJ, et al. A prospective study of obesity and risk of coronary heart disease in women. *N Engl J Med*. 1990;322:882-889.
5. Rimm EB, Stampfer MJ, Giovannucci E, et al. Body size and fat distribution as predictors of coronary heart disease among middle-aged and older US men. *Am J Epidemiol*. 1995;141:1117-1127.
6. Carey VJ, Walters EE, Colditz GA, et al. Body fat distribution and risk of non-insulin-dependent diabetes mellitus in women: the Nurses' Health Study. *Am J Epidemiol*. 1997;145:614-619.
7. Chan JM, Rimm EB, Colditz GA, Stampfer MJ, Willett WC. Obesity, fat distribution, and weight gain as risk factors for clinical diabetes in men. *Diabetes Care*. 1994;17:961-969. F. X. Pi-Sunyer, *Ann. Intern. Med.* 119, 655 (1993)
8. National Task Force on the Prevention and Treatment of Obesity. Overweight, Obesity, and Health Risk. *Arch Intern Med*. 2000; 160: 898 - 904.
9. Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: Increasing the value of clinical research for decision making in clinical and health policy. *JAMA*. 2003; 1624:1632.
10. Schwartz D, Lellouch J. Explanatory and pragmatic attitudes in therapeutic trials. *J Chronic Dis*. 1967;20:637-648.
11. Roland M, Torgerson DJ. What are pragmatic trials? *BMJ*. 1998;316:285.
12. Hsiao-Ling C. et al. Konjac supplement alleviated hypercholesterolemia and hyperglycemia in Type 2 Diabetic Subjects—A Randomized Double-Blind Trial. *J Am Coll Nutr*. 2003;22:36-42.
13. Willett WC, Dietz WH, Colditz GA. Guidelines for healthy weight. *NEJM*. 1999;341:427-434.
14. Biancardi, G. et al. Glucosamin in the treatment of overweight patients with osteoarthritis. *Current Therapeutic Research* 1989;46(5):908-912.
15. Walsh, DE, et al. Effect of glucosamin on obese patients: a clinical study. *International Journal of Obesity* 1984;8:289-293.
16. Reffo, GC., et al. Glucosamin in hypertensive outpatients: pilot clinical trial. *Current Therapeutic Research* 1988;44(1):22-27.
17. Reffo, GC., et al. Double-blind evaluation of glucosamin versus placebo in postinfarcted patients after cardiac rehabilitation. *Current Therapeutic Research* 1990;47(5):753-758.

18. Drapkin RG, Wing RR, Shiffman S. Responses to high-risk situations: Do they predict weight loss in a behavioral treatment program or the context of dietary lapses? *Health Psych.* 1995;14:427-434.
19. Grilo CM, Shiffman S, Wing RR. Coping with dietary relapse crises and their aftermath. *Addictive Behaviors* 1993;18:89-102.
20. Head S, Brookhardt A. Improving relapse-prevention strategies for weight loss. Paper presented at the meeting of the Society of Behavioral Medicine, 1996, San Diego, CA.
21. Baker RC, Kirshenbaum DS. Weight control during the holidays: Highly Consistent self-monitoring as a potentially useful coping mechanism. *Health Psych.* 1998; 17:367-370.
22. McDonald HP, Garg AX, Haynes RB. Interventions to enhance patient adherence to medication prescriptions: Scientific Review. *JAMA.* 2002;288:2868-2879.
23. Cherkin DC, Deyo RA, Battie M, et al. A comparison of physical therapy, chiropractic manipulation, and provision of an educational booklet for the treatment of patients with low back pain. *N Engl J Med.* 1998;339:1021-1029.
24. Cherkin DC, Eisenberg D, Sherman KJ, et al. Randomized trial comparing traditional Chinese medical acupuncture, therapeutic massage, and self-care education for chronic low back pain. *Arch Intern Med.* 2001;161:1081-1088.
25. Guyatt GH, Sackett DL, Cook DJ, for the Evidence-Based Medicine Working Group. Users' guides to the medical literature, II: how to use an article about therapy or prevention, B: what were the results and how will they help me in caring for my patients? *JAMA.* 1994;271:59-63.
26. Schroeder K, Fahey T, Ebrahim S. How can we improve adherence to blood pressure—lowering medication in ambulatory care. *Arch Int Med.* 2004. 164:722-732.
27. Haynes RB, McDonald HP, Garg AX. Helping patients follow prescribed treatment: Clinical applications. *JAMA.* 2002; 288:2880-2883.
28. Dans AL, Dans LF, Guyatt GH, Richardson S. for the Evidence-Based Medicine Working Group. Users' guides to the medical literature, XIV: how to decide on the applicability of clinical trials results to your patient. *JAMA.* 1998;279:545-54.
29. Bray GA. Medical consequences of obesity. *J Clin Endocrinol Metab* 2004; 89:2583-2589.
30. Klein S et. al. Absence of an effect of liposuction on insulin action and risk factors for coronary heart disease. *NEJM.* 2004; 350:2549-2557.
31. Losing A Few Pounds May Help The Obese, *The Associated Press*, June 1, 2004.

# Exhibit 3

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UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA

MARTIN CONDE, individually, and on behalf of  
all others similarly situated,

Plaintiff,

vs.

OBESITY RESEARCH INSTITUTE, LLC; and  
DOES 1-25, Inclusive,

Defendants.

Case No.: **CV12 - 0413 RSWL (RZx)**

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

Plaintiff MARTIN CONDE ("Plaintiff"), individually and on behalf of all others similarly situated, alleges the following on information and belief:

**I. INTRODUCTION**

1. Obesity Research Labs, LLC ("Defendant") manufactures, markets, and sells the Lipozene line of products ("the Products") as "safe and effective" weight loss products "clinically proven to reduce body fat." Defendant claims its Products are backed by "clinical studies" and research which supports the efficacy claims about their Products.

FILED

2012 JAN 17 PM 3:00  
CLERK U.S. DISTRICT COURT  
CENTRAL DIST. OF CALIF.  
SANTA ANA

BY FAX

4. Plaintiff brings this class action lawsuit to enjoin the ongoing deception of thousands of California consumers by Defendant, and to recover the money taken by this unlawful practice.

**A. Plaintiff.**

**B. Defendant.**

7. The true names and capacities, whether individual, corporate, associate, representative, alter ego or otherwise, of defendants and/or their alter egos named herein as DOES 1 through 25 inclusive are presently unknown to Plaintiff at this time, and are therefore sued by such fictitious names pursuant to California Code of Civil Procedure § 474. Plaintiff will amend this Complaint to allege the true names and capacities of DOES 1 through 25 when the same have been ascertained. Plaintiff are further informed and believe and based thereon allege that DOES 1 through 25 were

1 and/or are, in some manner or way, responsible for and liable to Plaintiff for the events, happenings,  
2 and damages hereinafter set forth below.

### 3 III. JURISDICTION AND VENUE

4 8. This Court has jurisdiction over the subject matter presented by this Complaint because  
5 it is a class action arising under the Class Action Fairness Act ("CAFA"), Pub. L. No. 109-2, 119 Stat.  
6 4 (2005), which explicitly provides for the original jurisdiction of the Federal Courts over any class  
7 action in which any member of the Plaintiff Class is a citizen of a state different from any Defendant,  
8 and in which the matter in controversy exceeds in the aggregate the sum of \$5,000,000, exclusive of  
9 interest and costs.

10 9. Plaintiff alleges that the total damages of the individual members of the Plaintiff Class  
11 in this action are in excess of \$5,000,000 in the aggregate, exclusive of interest and costs, as required  
12 by 28 U.S.C. § 1332(d)(2), (5).

13 10. As set forth herein, both Plaintiff and Defendant are citizens of California but the  
14 proposed class is nationwide and exceeds 100 individuals. Therefore, diversity of citizenship exists  
15 under CAFA, as required by 28 U.S.C. § 1332(d)(2), (5).

16 11. Venue is proper in this Court because Plaintiff purchased the Product in this Judicial  
17 District and because Defendant has received substantial compensation from sales in this Judicial  
18 District. Specifically, Defendant knowingly engages in activities directed at consumers in this Judicial  
19 District, and Defendant obtains substantial benefits from its scheme perpetrated in this Judicial  
20 District. The declaration of venue required by California Civil Code § 1780(d) is attached hereto as  
21 Exhibit 1.

### 22 IV. FACTS

23 12. Defendant manufactures, markets, and sells the Lipozene product line ("the Products")  
24 as a "safe and effective" way to lose weight that is "clinically proven to reduce body fat." Defendant  
25 claims its Products are backed by "clinical studies" and research which supports the efficacy claims  
26 about its Products. Based on Defendant's wide-spread marketing campaign, **Defendant claims to**  
27 **have sold "over 10 million bottles"** of its Products. (Emphasis added).  
28

13. Defendant makes numerous efficacy assertions on its website and via print, radio and television advertisements which Defendant states are supported by “clinical studies,” University testing and other “research.” Some of the claims include:

- (a) “CLINICALLY PROVEN TO REDUCE BODY FAT”;
- (b) “Weight Loss Guaranteed Results”;
- (c) “Lipozene diet pills are clinically proven to help reduce body fat & weight”;
- (d) “78% of each Pound Lost is PURE BODY FAT”;
- (e) “Lipozene diet pills are backed by multiple clinical studies”;
- (f) “REDUCE POUNDS of Body Fat and Weight WITHOUT a change in lifestyle”;
- (g) “Lipozene weight loss supplements are safe and effective”;
- (h) “Lipozene creates a dietary fiber sponge that makes you feel full, thus reducing caloric intake and adding fiber to your diet”;
- (i) “Lipozene guarantees you will lose weight and body fat”;
- (j) “The Obesity Research Institute has found the solution. It’s called Lipozene”;
- (k) “Lipozene is so powerful that it’s clinically proven to help you lose pure body fat”; and
- (l) Participants in the allegedly “major” University conducted, double-blind study “were not asked to change their daily lives. It’s so easy, just take Lipozene.”

(See Exhibit 2 attached depicting the numerous efficacy claims made by Defendant).

14. In reality, no reliable clinical research or University testing can support the above claims made by Defendant. Those “tests” and “studies” purportedly relied upon by Defendant are not named or identified by the Defendant, nor are the “Universities” or institutions that allegedly conducted them. “The bottom line: There’s simply no good evidence that the small doses of glucomannan offered by Lipozene could lead to significant weight loss, says Vladimir Vuksan, a

1 professor of nutritional sciences at the University of Toronto.”<sup>1</sup> In fact, for Defendant’s allegedly  
 2 active ingredient, glucomannan, to have any real effect as an appetite suppressant, “Vuksan estimates  
 3 that it would take 20 to 30 grams of glucomannan each day to achieve substantial weight loss, enough  
 4 to cause severe diarrhea and other gastrointestinal distress. Or, as Vuksan puts it, ‘your gut would  
 5 explode’.”<sup>2</sup>

6 15. Further, several studies which have examined the link between glucomannan and  
 7 weight loss have produced results that do not support, or even contradict Defendant’s claims about  
 8 Lipozene’s efficacy. For example, one study concluded that **glucomannan had no effect on weight**  
 9 **loss when compared to a placebo.**<sup>3</sup> In another study, glucomannan was only found to have a  
 10 statistical effect when it was coupled with resistance and endurance exercise and “healthy food  
 11 choices.”<sup>4</sup> In a review of studies on the effects of glucomannan and weight, the researchers  
 12 determined “Further investigation of safety, efficacy, and mechanisms of action is needed to  
 13 determine whether [glucomannan] can help to decrease the high prevalence of overweight and obesity  
 14 in the United States.”<sup>5</sup> In yet another study, glucomannan was only found to have an effect when it  
 15 was coupled with a *1200 calorie a day* diet for five weeks.<sup>6</sup>

16 16. Defendant’s exaggerated and/ or blatant misrepresentations regarding the efficacy of  
 17 their Products were designed to, and did, lead Plaintiff and others similarly situated (collectively the  
 18 “Class”) to believe that the Products were effective at providing weight loss and the reduction of fat.  
 19 Plaintiff and members of the Class relied on Defendant’s misrepresentations and would not have paid  
 20 as much, if at all, for the Products but for Defendant’s misrepresentations.

21 17. Plaintiff brings this class action lawsuit to enjoin the ongoing deception of thousands of  
 22 California consumers by Defendant, and to recover the money taken by this unlawful practice.

24 <sup>1</sup> Chric Woolston, “Bold claims for Lipozene, but not much evidence,” The Los Angeles Times (June 9, 2008), available at  
 25 <http://articles.latimes.com/2008/jun/09/health/he-skeptic9>.

26 <sup>2</sup> *Id.*

27 <sup>3</sup> Salas-Salvado, J. et al., “Effect of two doses of a mixture of soluble fibres on body weight and metabolic variables in  
 28 overweight or obese patients: a randomised trial,” Br. J. Nutr. (June 2008).

<sup>4</sup> Kraemer, W.J. et al., “Effect of adding exercise to a diet containing glucomannan,” Metabolism, (Aug. 2007).

<sup>5</sup> Kiethley, J., et al., “Glucomannan and obesity: a critical review,” Altern. Ther. Health Med. (Nov.-Dec. 2005).

<sup>6</sup> Birketvedt, G.S. et al., “Experiences with three different fiber supplements in weight reduction,” Med. Sci. Monit. (Jan. 2005).

1           18. Defendant sells the Products for approximately \$29.99 based on the preceding false  
2 advertising claims. As a result, Defendant has wrongfully taken millions of dollars from United States  
3 consumers.

4           19. Accordingly, Plaintiff brings this lawsuit to enjoin the ongoing deception of thousands  
5 of United States consumers by Defendant, and to recover the funds taken by this unlawful practice.

6                                   **V. CLASS ACTION ALLEGATIONS**

7           20. Plaintiff brings this class action for damages and other monetary relief on behalf of the  
8 following class:

9                   All persons located within the United States who purchased Lipozene  
10                   (1) from a retail location in California, or (2) over the internet at any  
11                   time after April 1, 2011 through the date of trial in this action (the  
12                   “Class”).

13           21. Excluded from the Class are governmental entities, Defendant, any entity in which  
14 Defendant has a controlling interest, and Defendant’s officers, directors, affiliates, legal  
15 representatives, employees, co-conspirators, successors, subsidiaries, and assigns, and individuals  
16 bound by any prior settlement involving Lipozene. Also excluded from the Class is any judge, justice,  
17 or judicial officer presiding over this matter and the members of their immediate families and judicial  
18 staff.

19           22. The proposed Class is so numerous that individual joinder of all its members is  
20 impracticable. Due to the nature of the trade and commerce involved, however, Plaintiff believes that  
21 the total number of Class members is at least in the tens of thousands and members of the Class are  
22 numerous and geographically dispersed across the United States. While the exact number and  
23 identities of the Class members are unknown at this time, such information can be ascertained through  
24 appropriate investigation and discovery. The disposition of the claims of the Class members in a  
25 single class action will provide substantial benefits to all parties and to the Court.

26           23. There is a well-defined community of interest in the questions of law and fact involved  
27 affecting the plaintiff class and these common questions predominate over any questions that may  
28

1 affect individual Class members. Common questions of fact and law include, but are not limited to,  
2 the following:

- 3 a. Whether Defendant's efficacy claims are accurate;
- 4 b. Whether Defendant's efficacy claims are properly substantiated;
- 5 c. Whether Defendant has falsely represented that Lipozene products have uses  
6 and benefits which they do not have;
- 7 d. Whether Defendant knew that its efficacy claims were false;
- 8 e. Whether Defendant's conduct constitutes a violation of the Consumers Legal  
9 Remedies Act (Cal. Civ. Code §§ 1750, *et seq.*);
- 10 f. Whether Defendant's conduct constitutes a violation of California's false  
11 advertising law (Cal. Bus. & Prof. Code §§ 17500, *et seq.*);
- 12 g. Whether Defendant's conduct constitutes an unfair, unlawful, and/or fraudulent  
13 business practice in violation of California's unfair competition law (Cal. Bus.  
14 & Prof. Code §§ 17200, *et seq.*);
- 15 h. Whether Plaintiff and Class members are entitled to compensatory damages,  
16 and if so, the nature of such damages;
- 17 i. Whether Plaintiff and Class members are entitled to restitutionary relief; and
- 18 j. Whether Plaintiff and Class members are entitled to injunctive relief.

19 24. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all  
20 members of the Class have been similarly affected by Defendant's common course of conduct since  
21 they all relied on Defendant's representations concerning the Products and purchased them based on  
22 those representations.

23 25. Plaintiff will fairly and adequately represent and protect the interests of the Class.  
24 Plaintiff has retained counsel with substantial experience in handling complex class action litigation.  
25 Plaintiff and his counsel are committed to vigorously prosecuting this action on behalf of the Class and  
26 have the financial resources to do so. Plaintiff has retained a law firm who is widely recognized as one  
27 of the most successful and effective class action litigators in California, and whose victories have been  
28

publicized on CNN, Fox News, MSNBC, and nearly every major California newspaper. The firm has also been certified as lead class counsel in similar class actions.

26. Plaintiff and the members of the Class suffered, and will continue to suffer, harm as a result of Defendant's unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the present controversy. Individual joinder of all members of the class is impracticable. Even if individual class members had the resources to pursue individual litigation, it would be unduly burdensome to the courts in which the individual litigation would proceed. Individual litigation magnifies the delay and expense to all parties in the court system of resolving the controversies engendered by Defendant's common course of conduct. The class action device allows a single court to provide the benefits of unitary adjudication, judicial economy, and the fair and efficient handling of all class members' claims in a single forum. The conduct of this action as a class action conserves the resources of the parties and of the judicial system and protects the rights of the class members. Furthermore, for many, if not most, a class action is the only feasible mechanism that allows an opportunity for legal redress and justice.

27. Adjudication of individual class members' claims with respect to Defendant would, as a practical matter, be dispositive of the interests of other members not parties to the adjudication, and could substantially impair or impede the ability of other class members to protect their interests.

## **VI. CAUSES OF ACTION**

### **FIRST CAUSE OF ACTION**

#### **VIOLATION OF THE CONSUMERS LEGAL REMEDIES ACT**

#### **(CAL. CIV. CODE §§ 1750, ET SEQ.)**

#### **(By Plaintiff and on Behalf of the Class Against Defendant)**

28. Plaintiff incorporates by this reference the allegations contained in the paragraphs above as if fully set forth herein.

29. Plaintiff has standing to pursue this cause of action because Plaintiff has suffered injury in fact and has lost money as a result of Defendant's actions as set forth herein. Specifically, Plaintiff purchased the Products in reliance on Defendant's marketing claims with respect to efficacy. Plaintiff

1 used the Products as directed, but it did not work as advertised and was not of the quality and standard  
2 advertised by Defendant.

3 30. Defendant has engaged in and continues to engage in business practices in violation of  
4 California Civil Code §§ 1750, *et seq.* (the “Consumers Legal Remedies Act”) by making false and  
5 unsubstantiated representations concerning the efficacy of the Products. These business practices are  
6 misleading and/or likely to mislead consumers and should be enjoined.

7 31. Defendant has engaged in deceptive acts or practices intended to result in the sale of  
8 Lipozene in violation of Civil Code § 1770. Defendant knew and/or should have known that its  
9 representations of fact concerning the efficacy of the Products were material and likely to mislead the  
10 public. Defendant affirmatively misrepresented that the Products were of a certain standard and  
11 quality with certain benefits which they did not have.

12 32. Defendant’s conduct alleged herein violates the Consumers Legal Remedies Act,  
13 including but not limited to, the following provisions: (1) using deceptive representations in  
14 connection with goods or services in violation of Civil Code § 1770(a)(4); (2) representing that goods  
15 or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which  
16 they do not have in violation of Civil Code § 1770(a)(5); and/or (3) advertising goods or services with  
17 intent not to sell them as advertised in violation of Civil Code § 1770(a)(9). As a direct and proximate  
18 result of Defendant’s conduct, as set forth herein, Defendant has received ill-gotten gains and/or  
19 profits, including but not limited to, money. Therefore, Defendant has been unjustly enriched.

20 33. There is no other adequate remedy at law, and Plaintiff and Class members will suffer  
21 irreparable harm unless Defendant’s conduct is enjoined.

22 34. In conjunction with filing this action, Plaintiff’s counsel mailed to Defendant, by  
23 certified mail, return receipt requested, the written notice required by Civil Code Section 1782(a). A  
24 copy of this letter is attached hereto as Exhibit 3. Should Defendant fail to respond within thirty days,  
25 Plaintiffs will amend to seek damages under the California Consumer Legal Remedies Act.

26 35. The declaration of venue required by Civil Code § 1780(d) is attached hereto as Exhibit  
27 1.

28 36. Defendant’s wrongful business practices constituted, and constitute, a continuing

1 course of conduct in violation of the Consumer Legal Remedies Act since Defendant is still  
2 representing that their Products have characteristics, uses, benefits, and abilities which are false and  
3 misleading, and have injured Plaintiff and the Class.

4 **SECOND CAUSE OF ACTION**

5 **VIOLATION OF CALIFORNIA'S FALSE ADVERTISING LAW**

6 **(CAL. BUS. & PROF. CODE §§ 17500, *ET SEQ.*)**

7 **(By Plaintiff and on Behalf of the Class Against Defendant)**

8 37. Plaintiff incorporates by this reference the allegations contained in the paragraphs  
9 above as if fully set forth herein.

10 38. Plaintiff has standing to pursue this cause of action because Plaintiff has suffered injury  
11 in fact and has lost money as a result of Defendant's actions as set forth herein. Specifically, Plaintiff  
12 purchased Lipozene in reliance on Defendant's marketing claims. Plaintiff used the Products as  
13 directed, but it did not work as advertised and did not provide any of the promised benefits.

14 39. Defendant has engaged in false advertising as they have disseminated false and/or  
15 misleading representations about the Products.

16 40. Defendant knew or should have known by exercising reasonable care that its  
17 representations were false and/or misleading. During the Class Period, Defendant engaged in false  
18 advertising in violation of Cal. Bus. & Prof. Code §§ 17500, *et seq.*, by misrepresenting in its  
19 advertising and marketing of the Products to Plaintiff, Class members, and the consuming public that  
20 its Products are effective.

21 41. Each of the aforementioned representations alleged in this Complaint was false and  
22 misleading because the Products are not of the standard, quality or grade advertised, and are in reality,  
23 ineffective.

24 42. By disseminating and publishing these statements in connection with the sale of the  
25 Products, Defendant has engaged in and continues to engage in false advertising in violation of Bus. &  
26 Prof. Code §§ 17500, *et seq.*

27 43. As a direct and proximate result of Defendant's conduct, as set forth herein, Defendant  
28 has received ill-gotten gains and/or profits, including but not limited to, money. Therefore, Defendant

1 has been unjustly enriched. Pursuant to Cal. Bus. & Prof. Code § 17535, Plaintiff requests restitution  
2 and restitutionary disgorgement for all sums obtained in violation of Cal. Bus. & Prof. Code §§ 17500,  
3 *et seq.*

4 44. Plaintiff seeks injunctive relief, restitution, and restitutionary disgorgement of  
5 Defendant's ill-gotten gains as specifically provided in Cal. Bus. & Prof. Code § 17535.

6 45. Plaintiff and Class members seek to enjoin Defendant from engaging in these wrongful  
7 practices, as alleged herein, in the future. There is no other adequate remedy at law and if an  
8 injunction is not ordered, Plaintiff and the Class will suffer irreparable harm and/or injury.

9 **THIRD CAUSE OF ACTION**

10 **UNLAWFUL, FRAUDULENT & UNFAIR BUSINESS PRACTICES**

11 **(CAL. BUS. & PROF. CODE §§ 17200, *ET SEQ.*)**

12 **(By Plaintiff and on Behalf of the Class Against Defendant)**

13 46. Plaintiff incorporates by this reference the allegations contained in the paragraphs  
14 above as if fully set forth herein.

15 47. Plaintiff has standing to pursue this cause of action because Plaintiff has suffered injury  
16 in fact and has lost money as a result of Defendant's actions as set forth herein. Specifically, Plaintiff  
17 purchased Lipozene in reliance on Defendant's marketing claims. Plaintiff used the Products as  
18 directed, but it did not work as advertised and were not of the standard, quality and grade advertised.

19 48. Defendant's actions as alleged in this Complaint constitute an unfair or deceptive  
20 business practice within the meaning of California Business and Professions Code §§ 17200, *et seq.*,  
21 in that Defendant's actions are unfair, unlawful, and fraudulent, and because Defendant has made  
22 unfair, deceptive, untrue, or misleading statements in advertising media, including the Internet, within  
23 the meaning of California Business and Professions Code §§ 17200, *et seq.*

24 49. Defendant knew or should have known by exercising reasonable care that its  
25 representations were false and/or misleading. During the Class Period, Defendant engaged in unfair,  
26 unlawful, and fraudulent business practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*,  
27 by misrepresenting in its advertising and marketing of the Products to Plaintiff, Class members, and  
28 the consuming public that, the Products were effective.

51. Defendant's business practices, as alleged herein, are unfair because they offend established public policy and/or are immoral, unethical, oppressive, unscrupulous, and/or substantially injurious to consumers in that consumers are misled by the claims made with respect to the Products as set forth herein.

53. Defendant's business practices, as alleged herein, are fraudulent because they are likely to, and did, deceive customers—including Plaintiff and members of the Class—into believing that the Products have characteristics and benefits they do not have.

55. As a direct and proximate result of Defendant's wrongful business practices in violation of Business and Professions Code §§ 17200, *et seq.*, Plaintiff and members of the Class have suffered economic injury by losing money as a result of purchasing the Products. Plaintiff and members of the Class would not have purchased or would have paid less for the Products had they known that they were not as represented.

## PRAYER FOR RELIEF

Plaintiff hereby demands a trial by jury of all claims and causes of action so triable in this lawsuit.

NEWPORT TRIAL GROUP  
A Professional Corporation  
Scott J. Ferrell


By: Scott J. Ferrell  
Attorney for Plaintiff and the Class

1 I, Martin Conde, declare as follows:

2 1. I am a Plaintiff in this action, and am a citizen of the State of California. I have  
3 personal knowledge of the facts herein and, if called as a witness, I could and would testify  
4 competently thereto.

5  
6 2. The Complaint in this action, filed concurrently with this Declaration, is filed in the  
7 proper place for trial under Civil Code Section 1780(d) in that LOS ANGELES County is a county  
8 in which Defendants are doing business.

9  
10 I declare under penalty of perjury under the laws of the State of California that the foregoing is  
11 true and correct.

12  
13   
14 Martin Conde

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LIMITED TIME OFFER:

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**30 DAY RISK FREE TRIAL LIMITED TIME OFFER:**



**Weight Loss Guaranteed Results**

**78% OF EACH POUND LOST IS PURE BODY FAT CLINICALLY PROVEN**

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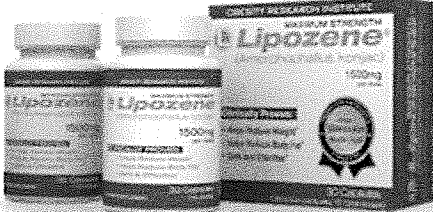
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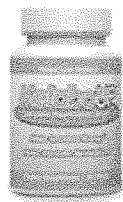
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**+**



Lipozene diet pills are clinically proven to help reduce body fat & weight

- 78% of each Pound Lost is PURE BODY FAT.
- Lipozene diet pills are backed by multiple clinical studies.
- REDUCE POUNDS of Body Fat and Weight WITHOUT a change in lifestyle
- Lipozene weight loss supplements are safe and effective

*As a surprise bonus for ordering today, we will also include our new energy boosting formula, Metabo Up, almost \$20 value, Free with your order. Metabo Up helps increase your metabolism and is the perfect way to maximize your results even faster!*

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**Lipozene** creates a dietary fiber sponge that makes you feel full, thus reducing caloric intake and adding fiber to your diet. Weight loss varies depending on each individual, but Lipozene guarantees you will lose weight and body fat, or your money back! Lipozene is 100% natural and there are no known side effects if taking Lipozene as directed. Lipozene contains Glucomannan, a 100% natural fiber from the Konjac Root. Lipozene is manufactured in the U.S.A. It is safe to take Lipozene up to 2 capsules, 3 times a day before each meal for a total daily maximum dosage of 6 capsules.

**\*Your personal information will never be disclosed to any third-party mailing list without your consent. By submitting information in this form, you agree that the information you provide will be governed by our site's Terms and Conditions.**

Clinical trials: Clinical trials are organized studies that test the value of various treatments to support health and nutrition in human beings.

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Lipozene - Facts

**Lipozene Facts That Every Dieter Should Know**

There are several Lipozene facts that every dieter should know as they work towards their weight loss goals. If you're struggling to lose weight, you could benefit greatly from this safe and natural product.

Lipozene is made from the Konjac root, most commonly known as Glucomannan. This water-soluble fiber that has been cultivated as a weight loss aid in Japan for generations acts as a sponge in your intestines and helps you feel full, so you eat less and as a result, reach your weight loss goals quicker. The most important of all the Lipozene facts is that it is 100% natural and does not cause harmful side effects when used as directed, but there's more.

When considering taking Lipozene, it's important to understand the facts and forget all the fiction. While many products claim to provide a host of benefits, from weight loss to stronger nails and pretty much everything else you can imagine, Lipozene has been clinically proven to provide the benefits it claims, without making major lifestyle changes that can be potentially harmful to your system. There are even studies that connect its main ingredient Glucomannan with alleviating constipation, reducing cholesterol and regulating blood sugar. Those are the facts.

Clinical trials: Clinical trials are organized studies that test the value of various treatments to support health and nutrition in human beings.

Disclaimer: The products and the claims made about specific products on or through this site have not been evaluated by the United States Food and Drug Administration (FDA) and are not approved to diagnose, treat, cure or prevent disease.

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# NEWPORT TRIAL GROUP

A Professional Corporation

895 Dove Street, Suite 425  
Newport Beach, CA 92660  
Phone (949) 706-6464  
Fax (949) 706-6469  
www.trialnewport.com

January 17, 2012

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Obesity Research Institute, LLC  
2032 Corte Del Nogal  
Suite 110  
Carlsbad, CA 92011

Obesity Research Institute, LLC  
17185 Via Barranca del Zorro  
Rancho Santa Fe, CA 92067

*Re: Violations of California Consumer Protection Laws*

Dear Sir or Madam:

I am writing on behalf of an individual California consumer, as well as a putative class of similarly situated consumers, to advise you that we believe you are violating the California Consumer Legal Remedies Act.

Specifically, you market "Lipozene" as a "safe and effective" weight loss product that is "clinically proven to reduce body fat" and that it provides "Weight Loss" with "Guaranteed Results." You claim it is "clinically proven" that when consumers use Lipozene, "78% of each pound lost is pure body fat." You go so far as to claim that the "Lipozene diet pills are clinically proven to help reduce body fat & weight," that "Lipozene diet pills are backed by multiple clinical studies," and that with Lipozene, users can "REDUCE POUNDS of Body Fat and Weight WITHOUT a change in lifestyle." Our client relied on these assertions and did not experience any of the promised benefits. In fact, your product was completely worthless to him.

The preceding claims are false and misleading, and are not supported by competent and reliable scientific evidence. In reality, Lipozene's allegedly "active ingredient" is merely fiber and has never been scientifically substantiated as being able to provide weight loss benefits, especially not to the extent claimed. Further, the "clinical studies" that you allege support your outlandish weight loss claims with respect to Lipozene do not show Lipozene can provide weight

January 17, 2012

Page 2

loss. If anything, the studies merely show that with lower caloric intake and increased exercise, people can lose weight. This conclusion is not new or novel and does nothing to support your claims that Lipozene can cause weight loss or reduce body fat. In sum, the manner and presentation of your marketing leaves consumers with a misleading overall net impression regarding Lipozene.

As such, we believe that you are advertising Lipozene as having characteristics, uses and benefits that it does not have in violation of the Consumer Legal Remedies Act. We further believe that the aforementioned representations regarding the purported benefits, qualities and characteristics of Lipozene constitutes a violation of California's False Advertising Law (Cal. Bus. & Prof. Code § 17500 *et seq.*) and a violation of California's Unfair Competition Law (Cal. Bus. & Prof. Code § 17200 *et seq.*).

We respectfully request that you agree to irrevocably stop all false and misleading advertising and labeling of this and similar products marketed and that you provide all consumers who have purchased the product with a full refund. If you conform your activities to comply with California law, we will take no further action in this matter. We invite you to contact us to further discuss and resolve this matter.

Very truly yours,

NEWPORT TRIAL GROUP  
A Professional Corporation



Scott J. Ferrell

SJF:cl

# Exhibit 4



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TRY IT FOR 30 DAYS!

Try Lipozene Now !

United States

Select State

Try it Now

[Loss Weight or your money back](#)

TRY LIPOZENE TODAY!

MANUFACTURER'S SPECIAL OFFER,  
NOT AVAILABLE IN STORES

BUY 1 GET ONE FREE!

plus a FREE GIFT of  
MetaboUP Plus & FREE S&H

## Lipozene Clinical Studies

Numerous clinical studies confirm Lipozene's active ingredient, Glucomannan, is safe and effective for weight loss and body fat loss.

### EFFECT OF GLUCOMANNAN ON OBESE PATIENTS: A CLINICAL STUDY

David E. Walsh, Vazgen YAGHOUBIAN and Ali BEHFOROZ

An eight-week double-blind trial was conducted to test purified glucomannan fiber as a food supplement in 20 obese subjects. Glucomannan fiber (from konjac root) or placebo was given in 1-g doses (two 500 mg capsules) with 8 oz water, one hour prior to each of three meals per day. Subjects were instructed not to change their eating or exercise patterns. Results showed a significant mean weight loss (5.5 lbs) using glucomannan over an eight-week period. Serum cholesterol and low-density lipoprotein cholesterol were significantly reduced (21.7 and 15.0 mg/dl respectively) in the glucomannan treated group. No adverse reactions to glucomannan were reported.

[DOWNLOAD FULL STUDY](#)

### GLUCOMANNAN AND OBESITY: A CRITICAL REVIEW

Joyce Keithley, DNSc, RN, FAAN, Barbara Swanson, DNSc, RN, ACRN

Glucomannan (GM) is a soluble, fermentable, and highly viscous dietary fiber derived from the root of the elephant yam or konjac plant, which is native to Asia.

Preliminary evidence suggests that GM may promote weight loss. This review summarizes studies using GM for weight loss as well as studies investigating its mechanisms of action. At doses of 2-4 g per day, GM was well-tolerated and resulted in significant weight loss in overweight and obese individuals. There is some evidence that GM exerts its beneficial effects by promoting satiety and fecal energy loss. Additionally, GM has been shown to improve lipid and lipoprotein parameters and glycemic status. Further investigation of safety, efficacy and mechanisms of actions is needed to determine whether GM can help to decrease the high prevalence of overweight and obesity in the United States. (Altern Ther Health Med.

2005;11(6):30-34.)

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### EFFECT OF GLUCOMANNAN ON PLASMA LIPID AND GLUCOSE CONCENTRATIONS, BODY WEIGHT, AND BLOOD PRESSURE: SYSTEMATIC REVIEW AND META-ANALYSIS

Nitesh Sood, William L. Baker, and Craig I Coleman

More than 50 million Americans are thought to suffer from the metabolic syndrome, which is characterized by a group of metabolic risk factors occurring in a single individual, including but not limited to abdominal obesity, atherogenic dyslipidemia, elevated blood pressure, and insulin resistance or glucose intolerance (1). Patients with the metabolic syndrome are at increased risk of coronary heart disease, stroke, and peripheral vascular disease as well as type 2 diabetes mellitus. According to the American Heart Association, the primary goal for the management of patients with the metabolic syndrome is to reduce their risk of cardiovascular disease and type 2 diabetes through smoking cessation and by reducing LDL cholesterol, blood pressure, body mass index, and glucose to recommended levels (1). Glucomannan is a soluble fiber derived from *Amorphophallus konjac* and is available in numerous over-the-counter products such as Lipozene. Like other soluble fiber (oats, guar gum, pectin, and psyllium), glucomannan has been touted for its potential beneficial effects on the risk of coronary heart disease (2). Glucomannan is thought to prolong gastric emptying time, which increases satiety, reduces body weight, decreases the ingestion of foods that

increase cholesterol and glucose concentrations, reduces the postprandial rise in plasma glucose, suppresses hepatic cholesterol synthesis, and increases the fecal elimination of cholesterol

containing bile acids (2). Several clinical trials (3–19) have investigated the impact of glucomannan on total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, body weight, fasting blood glucose (FBG), systolic blood pressure (SBP), or diastolic blood pressure (DBP), but have yielded conflicting results and had only modest sample sizes. Although previous meta-analyses assessing the effects of soluble fibers on these same endpoints have been published, none have evaluated glucomannan. Therefore, we conducted a meta-analysis of randomized controlled trials of glucomannan to better characterize its impact on various characteristics of the metabolic syndrome.

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OFFER DETAILS: Manufacturer's Special Offer - Buy one bottle of Lipozene for only \$29.95 and get a 2nd bottle FREE! There is no shipping or handling charge for your purchase, just a \$1.35 processing fee. All purchases are backed by our 30 Day NO QUESTIONS ASKED MONEY-BACK GUARANTEE. If you are not satisfied for ANY reason, simply return your purchase within 30 days of the ship date and we will issue you a FULL REFUND! (Minus the \$1.35 processing fee)

\*America's # 1 Diet Pill claim is based on IRI Sales Data published on January 25, 2015 and based solely on single SKU data.

\*\*Clinical data shows that the difference in the amount of weight loss experienced between the active and placebo group was 4.93 LBS.

\*\*\*Results not typical average weight loss experienced between the active and placebo group was 4.93 LBS. Testimonials were remunerated for their time and their results were achieved in combination with diet and exercise.

\*\*\*\* Recommended to be taken with 32 oz. glass of water.

† These statements have not been evaluated by the Food and Drug Administration. This product in not intended to diagnose, treat, cure or prevent any disease.

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# Exhibit 5

**Japan Food Research Laboratories**

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No. 14131746001-01 1/1

January 19, 2015

**CERTIFICATE OF ANALYSIS**

Client: SHIMIZU CHEMICAL CORPORATION  
4-5-1, Kihara, Mihara-Shi, Hiroshima-Ken, 729-0321 Japan

Sample name: Lipozene (Lot No. 424597)

Received date: December 23, 2014

This is to certify that the following result(s) have been obtained from our analysis on the above-mentioned sample(s) submitted by the client.

**Test Result(s)**

Test Item	Result	QL	N	M
Glucose	34.1 g/100g	.....	1	1
Mannose	45.4 g/100g	.....	1	1
Galactose	0.6 g/100g	.....	1	1
Glucuronic acid	0.2 g/100g	.....	1	1
Investigation of sugars	.....	.....	2	1
Mannose	(+)	.....		
Arabinose	(-)	.....		
Galactose	(+)	.....		
Xylose	(-)	.....		
Glucose	(+)	.....		
Rhamnose	(-)	.....		
Ribose	(-)	.....		
Fucose	(-)	.....		
Glucuronic acid	(+)	.....		

QL: Quantitation limit N: Notes M: Method

**Notes**

1: Acid hydrolysis was performed before measurement. Hydrolysis conditions: stirred in 72 % sulfuric acid at room temperature for 1 hour and autoclaved (121 °C) in 4 % sulfuric acid for 1 hour.

2: The result (+) means not less than 0.2 %. Acid hydrolysis was performed before measurement. Hydrolysis conditions: stirred in 72 % sulfuric acid at room temperature for 1 hour and autoclaved (121 °C) in 4 % sulfuric acid for 1 hour.

**Method**

1: HPLC



*T. Arai*  
Takeko Arai  
Principal Investigator

*Jan. 19, 2015*  
Date

# Exhibit 6



**SHIMIZU**

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QUALITY CONTROL  
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Apr. 01, 2014

**CERTIFICATE OF ANALYSIS**

COA No.5005

Sample: Lipozene

This is to certify that the following results have been obtained  
by our analysis on the above-mentioned samples.

Result :

Lot No.	380114	423915
Sulfite (SO <sub>2</sub> )	36ppm	36ppm



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Aug. 07, 2014

**CERTIFICATE OF ANALYSIS**

COA No.5025

Sample: Lipozene (Lot No.425074)

This is to certify that the following results have been obtained  
by our analysis on the above-mentioned samples.

Result :

Sulfite (SO <sub>2</sub> )	102ppm
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**SHIMIZU**

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Oct. 31, 2014

**CERTIFICATE OF ANALYSIS**

COA No.5046

Sample: Lipozene (Lot No.425907)

This is to certify that the following results have been obtained  
by our analysis on the above-mentioned samples.

Result :

Sulfite (SO <sub>2</sub> )	92ppm
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Nov. 21, 2014

## CERTIFICATE OF ANALYSIS

COA No.5052

Sample: Lipozene (Lot No.424597)

This is to certify that the following results have been obtained  
by our analysis on the above-mentioned samples.

Results :

Sulfite (SO <sub>2</sub> )	147ppm
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Product image

